IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs. No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Defendant.

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REPORTER'S TRANSCRIPT OF PROCEEDINGS

PRETRIAL CONFERENCE

TUESDAY, JUNE 5, 2018, 1:30 P.M.

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HUNTINGTON, WEST VIRGINIA

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THE COURT: Good afternoon.

MR. CHILDERS: Good afternoon, Your Honor.

MR. IMBROSCIO: Good afternoon, Your Honor.

MR. MOSKOW: Good afternoon, Your Honor.

THE COURT: Welcome back.

MR. MOSKOW: Thank you.

THE COURT: All right. We have a number of motions that remain pending that I want to go through here and argue about first. After we have concluded arguing all of the pending motions, there are a few matters I want to discuss with you, sort of the logistics in anticipation of the future pretrial conference and trial date as altered by the Court.

So I think what I'd like to do is start first with the defendant's motions in limine with respect to the general experts of plaintiffs.

Have you already noted your appearances? Do you have them marked?

THE COURT REPORTER: I have them.

THE COURT: All right. Go ahead.

MR. LEWIS: Good afternoon, Your Honor. John Lewis for the defendant. Thank you for the opportunity to be heard on these motions, Your Honor.

We essentially, Your Honor, are making a motion related to plaintiff's experts in three what I'll call broad categories, plaintiff's experts related to what I'll call plasma monitoring --

THE COURT: Right.

MR. LEWIS: -- secondly with respect to labeling, and then thirdly with respect to corporate intent, corporate knowledge, corporate behavior if you will.

Unless the Court has a particular order --

THE COURT: No, that sounds good.

MR. LEWIS: -- I'm just going to roll into the way our briefing was structured, which is focus first on the plasma monitoring.

And the reason we're asking the Court for relief here with respect to plaintiff's experts and their opinions related to plasma monitoring really kind of falls into two big categories.

The first is, there's a real fit problem here with respect to these opinions. And when I say fit, I mean that the opinions are sort of in an abstract way what they are. But when we peel the onion back a little bit closer to the facts of this case, we see that those general opinions related to plasma monitoring don't appear to be connected to the plaintiff's specific case here in a sufficient way to allow them to be admissible. And we can kind of talk broadly about

why that is so.

In this particular case, what we lack here on a case specific -- from a case specific perspective is evidence that whatever it is that the plaintiff's experts say we should have done differently with plasma monitoring, that it actually would have led to a different and better result for Ms. Knight in this particular case.

Now what we do have -- and I acknowledge Your Honor's summary judgment ruling, which I've spent a lot of time on. We do have somewhat light -- what I'll call lighter testimony from some of the treaters that they would have considered, right, the possibility of monitoring guidance or something along those lines. But in order for the general opinions to be admissible, we really need a little bit more than that.

What we need to have to fit the case is for someone to come in and to say, if this particular plaintiff had been monitored appropriately, pursuant to whatever the plaintiff's experts say we should have done to give them the benefit of the doubt for right now, then it would have led to a different clinical outcome for the plaintiff. All we have in the record right now is that it would have been considered, not that any physician would have actually made a different choice.

And if we really look at the plaintiff's circumstances here -- and I know Your Honor has looked at this because, in the summary judgment opinion, the medical history of the

plaintiff is laid out in very, very -- in a lot of detail.

We know that Ms. Knight, at the time that she had her bleed incident that was the subject injury here, had had stents and was on triple therapy with these other medications. And what we lack is any physician coming in and saying, you know what, if I'd had known better to monitor this particular individual, I would have instead prescribed Warfarin, for instance. Or I would have taken her completely off Pradaxa and allowed her to just go forward without Pradaxa at all if her levels got to a certain point. We lack any testimony, ah, to that effect in this case.

THE COURT: Well, what about, though, the evidence that I cited in the summary judgment ruling where we discussed Dr. Ashhab, Dr. MacFarland, the cardiologist? It's not the strongest, clearest evidence, but nonetheless I found it was sufficient to create an issue of fact. And each of those doctors testified in a way that if the label or other information had told them of these significantly apparently quantifiable increases in risk given this constellation of medications and symptoms had been conveyed to -- had been then conveyed to us that you ought to be checking plasma levels when somebody goes on this, they all said in one way or another that they would have, or at least they may have.

I want to know why that -- it seems to me if it's enough for the ruling on summary judgment, why isn't it enough

here on getting these opinions in?

MR. LEWIS: Right.

Well, Your Honor, I respect the Court's summary judgment opinion, and I have to obviously. But when we're talking about the admissibility of expert opinion, we're really working under a different paradigm.

Instead of a material issue of fact for the jury --

THE COURT: Right.

MR. LEWIS: -- we're now working under the Daubert paradigm.

And the Daubert paradigm does require an analysis separate and independent of any summary judgment analysis that the expert's opinions fit the case to the point where the jury can hear these folks testify as scientific experts and be able to rule -- to enter a verdict in the case based on that testimony.

That's different than saying, hey, you know what, jury, you're just going to have to figure out whether Dr. Abdelgaber or Dr. MacFarland actually would have done something differently. That's fine. Understood. Respect the Court's opinion on that. But we are really talking about the admissibility of experts, and that has a different impact on juries when an expert is up there, and the Court has said this is an expert opinion, what have you. The law does require that there be a connection to the case sufficient that it

would have changed the outcome in the case, it would have assisted the jury in helping to evaluate the plaintiff's allegations in this case, and we don't have that here.

There is no expert who actually connects the monitoring opinion to a changed clinical outcome. Even the testimony that the Court cited in the summary judgment motion -- again, respect that the jury is going to be able to consider that -- even that testimony isn't a sufficient basis to have the experts come in and testify about the different ways we should have warned physicians on how to monitor because there is no evidence that monitoring would have led to a different outcome here. There just isn't.

Even in the Court's opinion, even in the Court's opinion, there is no suggestion, there is no evidence cited that this particular plaintiff would have been on a different medication or even had changed -- a changed medical outcome because of that. That's big problem number one.

THE COURT: Okay. You've got -- it's the same argument concerning each of the monitoring opinions that you criticized, Dr. --

MR. LEWIS: Absolutely.

THE COURT: Is it Baruch? Is that how you say his name?

MR. LEWIS: Baruch, I think.

THE COURT: Yeah, Dr. Baruch. And then the other two

as well.

MR. LEWIS: Right, which I think also include, I guess, Laura Plunkett and Dr. Chernow [phonetic] --

THE COURT: Yeah.

MR. LEWIS: -- on the monitoring.

The other piece of really our challenge here is -- and I guess I'll tackle these in two different ways. Let's focus first on Dr. Baruch.

Again, peeling the onion back a little bit as we must do when we are talking under the Daubert paradigm, Dr. Baruch really isn't bringing anything to bear here that he's done independently. In fact, the things that he cites are really just Boehringer documents or FDA documents that -- I mean, his deposition was pretty clear.

He didn't even really understand the models that he was citing in his --

THE COURT: But does he have to? I mean, isn't it enough that the expert testifies that he relied upon the type of data and material that experts in his field typically rely upon, even if it's not otherwise independently admissible and even if he can't really explain it?

I mean, that's -- one facet of having expertise is that you know what you can rely upon and use and should take into consideration. That doesn't mean that you have to be the person that produced that data or that analysis or even

understand it fully. If it's what experts of your type use and rely upon, that's enough.

MR. LEWIS: And I would -- Your Honor, perhaps the first part about admissibility, definitely agree with you there, that not all of the evidence has to be admissible, but the expert has to understand it.

And the reason why the expert has to understand it is if he doesn't, as Dr. Baruch clearly doesn't here, and I think he kind of admits that --

THE COURT: And, you know, I'm going to confess that it's been hard to keep all of these straight, and I haven't reread this part very recently. But are there specific BI models or studies or something that in particular you believe Dr. Baruch said I don't know what that -- I can't explain that, but I nonetheless relied upon it?

MR. LEWIS: Yes.

So on page 4 of our opening brief, we sort of talk about the -- we cite the areas where he sort of made these admissions that he doesn't have an understanding as to the modeling that he's testified about, which lead him to the conclusion that, oh, you should have offered this monitoring guidance, and here's the specific monitoring guidance you should have offered. He's not -- he admits that he doesn't understand how this was derived or arrived at.

And I guess I would sort of twist it around the other

way. There is -- if Dr. Baruch doesn't understand how he's arriving at his opinion, I don't see how that makes him an expert in any way, shape or form. And I think that's exactly what Daubert is saying the Court needs to make sure that we don't let someone get on the stand and start overly persuading the jury as an expert when they don't fundamentally understand what they're talking about, and instead they are just serving as a conduit or a mouthpiece for maybe an argument.

I'm not saying that the plaintiffs can't make the argument during the trial using the BI documents and the FDA documents to support that. But when you take it to the next level, which is offer an expert opinion on that that's very persuasive to a jury, that is where the Court comes in and says, look, that person, he or she has to understand what he or she is talking about. And that's what Dr. Baruch doesn't understand here.

When we dive further into Dr. Baruch, we also see that he's -- he has been completely inconsistent on his viewpoints throughout time. Now, I understand that's probably an issue of -- because a lot of courts -- I've been in these Daubert hearings --

THE COURT: Now you're talking about the different numbers he gave or the different ranges?

MR. LEWIS: The different numbers and even some of his public statements have been inconsistent with statements he's

now making in this litigation.

I know a lot of judges would say -- including Judge Land, the Middle District of Georgia, who ruled on the Chambers case, a lot of judges will say, oh, tackle that on cross-examination, and I get that. I mean, I understand that some courts have that view.

But it seems to me that in this circuit, having read and reviewed -- I know Your Honor is familiar with that Nease case that is recent, that Ford Motor case. It seems to me that the Fourth Circuit is saying we need to have a little bit more scrutiny of experts than just sort of allowing things to happen on cross-examination in front of the jury.

And Dr. Baruch doesn't seem to have a very consistent methodology --

THE COURT: What do you think plaintiff's theory is with respect to this whole question about the plasma concentration levels and the ranges and so forth?

As I understand it, the plaintiffs concede they're not trying to prove as part their theory that there is some specific range. But, rather, their point is there ought to be some guidance from the manufacturer, and then it's the manufacturer who ought to know where the therapeutic range is and what is too high or too low.

And so Dr. Baruch is -- I mean, I think some of his inconsistency in reporting different ranges arises from the

fact that he was trying to answer questions, essentially being cross-examined in his deposition, and that he wasn't really saying this is my precise opinion I'm going to testify to at trial. I'm just trying to answer your questions. You've asked me why I think there ought to be monitoring and what the manufacturer should instruct patients and doctors to do with respect to monitoring and how to monitor. But I don't really think that he was going so far as to say here's what that monitoring should reveal, and this is the precise therapeutic range that that monitoring ought to target.

MR. LEWIS: In his depo, he did -- he provided some ranges. Now, again, maybe that was just because he was pressed. If the Court would rule that he's not allowed to offer those opinions in specific ranges in the trial, I'm going to accept that, that ruling obviously.

But --

THE COURT: You can give that up, not cross-examine him about the variations that he used in the ranges?

MR. LEWIS: Well, here's I guess the point and why it ties back to fit and why I'm fussing so much about the fit in the case.

Because if the opinion really isn't that there's a specific range, just that the company should have offered some vague guidance to monitor plasma levels, okay. So how would that have mattered in Ms. Knight's case, vague guidance about

monitoring?

If the expert opinion is I don't have any ranges wherein the doctor should take action, I just think plasma levels should be monitored, okay, fine. If that is your theory, fine. How would that have mattered in Ms. Knight's case?

Because the reality is is that we don't have data on her plasma levels just before the bleed. We have some data, but we don't have data just before the bleed incident.

More importantly, we don't -- even if we allow Dr. Ashhab's extrapolation, right, to go back in time and say, oh, well, her levels would have been X, Y or Z at the time of the bleed, which is what essentially his opinion is, to extrapolate --

THE COURT: Right.

MR. LEWIS: -- the opinions of these experts don't indicate that that would have mattered.

If her level was 150, if her level was 200, whatever it is, the opinions of the plaintiff's experts that some monitoring should have been done doesn't really affect the outcome of this case. Because you're not -- the plaintiffs are not suggesting that, oh, the plaintiff would have fallen within this danger zone that would have required action. And if action were taken, then you would have prevented a bleed incident and would have taken her off Pradaxa or something

along those lines.

So, again, that's another problem with the fit here --

THE COURT: Okay.

MR. LEWIS: -- is when you start to play out the logical chain of the theory.

And so when Your Honor asked me, well, what is the plaintiff's theory on plasma monitoring, I gotta be honest, it's kind of all over the board. I mean, we have three different experts kind of saying three different things. It doesn't really match up to what the treaters are saying. And that's our big problem with this whole plasma monitoring piece.

THE COURT: Okay. All right. I'll look forward to hearing their response in explaining that part of their case.

Let's shift, then, to the labeling opinion.

MR. LEWIS: Sure.

So when we talk about labeling, Your Honor, we're really kind of focused on -- and I'll try to articulate what I think the rule is here --

THE COURT: Okay.

MR. LEWIS: -- in this district.

And this is really premised on some decisions from Judge Goodwin and perhaps some other Fourth Circuit law on this particular point. And I'm just focusing specifically on Judge Goodwin's decisions in the Ethicon, Husky and Bard

cases.

The rule is essentially this, it is a three-step process. Step one is related to qualifications. Do you make clinical judgments yourself? Do you prescribe this particular product or class of products? If you don't, then you're not qualified to talk about what should and shouldn't be in the label for some other physician to make a decision about.

If you have never even yourself had to make this decision, then you really don't have the qualifications to indicate what some other physician might feel is important or not from a risk benefit perspective. That seems to be a pretty fundamental proposition.

I have found very few cases even in West Virginia where someone has tried to proffer somebody like, ah, plaintiff's expert Gosselin, who has never even made a decision himself on how to prescribe a particular class of products or this particular medication to a patient -- he is a laboratory person, so in that sense, Dr. Gosselin doesn't even meet these minimal requirements to be qualified to be talking about what should be in and out of the label. Obviously his opinions may be admissible for other purposes, but not in an effort to criticize the label in the first instance.

THE COURT: Did Dr. Baruch fall in that same category? Or did he testify that he has clinical experience with treating people who are -- either through prescribing these

medications or treating people who were on them?

MR. LEWIS: Dr. Baruch would be -- would meet that minimal qualification.

Dr. Baruch obviously makes decisions on how to prescribe these types of --

THE COURT: You agree that Dr. Chertow does as well, the nephrologist?

MR. LEWIS: Both of those doctors meet that minimum requirement. I would say Dr. Gosselin, he is out because he doesn't even make that --

THE COURT: Well, let's focus on him a little bit because, as I understand it, he's essentially what I would characterize generally as a research scientist.

MR. LEWIS: Right.

THE COURT: And so why is it that if he's a research scientist, who admittedly his expertise is in the area of coagulation and anticoagulation and the effects, efficacy and characteristics of these things -- I mean, that seems to me that gives him expertise to know what the risks are or be able to evaluate reports of what the risks are for a given medication and compare that to what is stated in the labeling or patient medication guides and say whether or not the labeling or the guides convey what he determines as a research scientist to be fairly the risks and benefits or whatever of a particular drug therapy.

MR. LEWIS: Right. So here is why that doesn't work.

And I'll just call -- as a lab guy or as a research scientist, he may be qualified to talk about here are the risks, here are the benefits of this particular drug or medicine. Totally fine. But when you get into the arena of what ought to be disclosed to physicians in a label for the risk benefit analysis, it takes that information to a different level.

Because we know that not all risks, not all benefits work themselves into a label, nor should they. Nor should the way that they're framed into a label be in a generic way.

This needs to be framed in an appropriate way for a physician to take that information --

THE COURT: But didn't he testify -- and perhaps this is laid out also in his CV, his qualifications, but that part of his role at whichever university -- is it a university hospital?

Is that where he is or --

MR. LEWIS: I think that's --

THE COURT: Wherever it was, but that he did advise clinicians about these matters?

MR. LEWIS: Well --

THE COURT: So while admittedly he's not writing prescriptions, he's not directing treatment, if he is -- if he is advising clinicians about the risks and efficacy of

different blood thinners and all that, it seems to me he's sufficiently familiar with what is conveyed in labels and medication guides to be able to testify about whether they reveal the risks and benefits that he assesses.

MR. LEWIS: I'd urge the Court to take a look at his deposition around pages 118 and 119. We cite that on page 14.

THE COURT: Okay.

MR. LEWIS: I will say this. If you compare Mr. Gosselin to Dr. Baruch -- now, Dr. Baruch shouldn't be able to offer these opinions, but it's for a different reason. But for the fundamental qualification issue, you see a vast difference in those two individuals, and you see why Mr. Gosselin really isn't an expert for labeling and really isn't an expert for advising physicians.

Sure, he has some cursory conversations with emergency room physicians. But it is not his job and it is not his primary job to be advising physicians on how to prescribe Pradaxa or to make decisions about how to treat patients who have been prescribed Pradaxa.

If you read his deposition, he's almost grasping for straws on coming up with some information, some experience, and certainly not the type of experience that would lend oneself to be an expert able to testify.

THE COURT: Okay. I'll certainly take a look at those.

MR. LEWIS: Rule number one, do you make clinical judgments yourself and prescribe this? That's kind of a fundamental base for qualifications. According to Judge Goodwin, that's just not enough either. You have to have something extra, and Judge Goodwin has sort of made this -- drawn this line.

If you are -- you have to fundamentally be a physician, otherwise makes clinical judgments, prescribes yourself, and then you have to have some other kind of experience or training. Maybe you have helped with labels. Maybe you know a little bit about FDA labeling or you've done your own work on that particular issue.

Or like in -- and I'll even say in I think it was the Husky case, a urogynecologist -- because it was a vaginal sling case -- was a pioneer in the industry, went around talking and teaching other physicians about the risks and benefits of the device in addition to making these clinical judgments himself. Judge Goodwin said, you know, that's the something extra I am looking for in a physician.

When we look at Dr. Chernow, while he may have these baseline qualifications, he lacks this second piece, this something extra. He's really not offering any experience in teaching other physicians. He's not an FDA labeling expert or worked for the FDA obviously. And he's really not even familiar with the regulations that the FDA uses with respect

to labeling.

He seemed very unfamiliar, and again on page 15 of our brief, we cite a couple of excerpts from his deposition where he really gave that up. He really conceded that this isn't really his thing, labeling for physicians. He's not that kind of guy. And so Dr. Chernow really misses the mark with respect to this something extra that Judge Goodwin, ah, has required in order to allow labeling opinion testimony in cases.

THE COURT: I made a note here when I was reading through these, and I think that plaintiff responded at least in part by saying with respect to Dr. Chernow -- is it Chertow?

MR. MOSKOW: It is, Your Honor.

THE COURT: That Dr. Chertow is really focused on discussing the labeling with respect to the interaction with the kidney, which he's a nephrologist, and different types of coagulants and coagulation activities. So, I mean, that seems to me to be right in the ballpark for him, that he's a nephrologist, and he's going to testify that he knows and understands how coagulant activity is affected by kidney function.

What more does he need? He's discussing the labeling because the labeling purports to discuss and explain the relationship between kidney function and coagulation activity.

And if that is what he's testifying about, it's not really a matter of whether he has some specialized knowledge in labeling decisions, it's his specialized knowledge in kidney function, in nephrology.

MR. LEWIS: And, Your Honor, I think that's where I would disagree respectfully.

THE COURT: Okay.

MR. LEWIS: There's a difference between having knowledge of a particular subject matter or even a clinical area and then being an expert in relaying knowledge or information or assistance or guidance with respect to clinical decision-making. There is a distinction between them.

Certainly one can have a lot of knowledge about something, but they have to be an expert in relaying that information, teaching, coaching, educating others on how to make those decisions themselves, and that's where Dr. Chernow just does not have it.

Certainly he has the knowledge, no question about that. But as Judge Goodwin said in the Ethicon case with this Dr. Margolis, he was really -- Dr. Margolis in the Ethicon case was really sort of the same or the equivalent of Dr. Chernow. I mean, he was a gynecologist. He had lots of information about how these things worked and treated plenty of patients on his own, but he didn't have that extra thing in his background that gave him the expertise to be able to say

here's how you teach other people how to do this. Here's how you provide guidance to other people. Here's how FDA labeling requirements work and the rules associated with that. That extra thing is what is missing here also with Dr. Chernow. That's the fundamental flaw.

I grant you that he does have clinical knowledge and experience. He just doesn't have the experience of teaching others how to make those judgments themselves.

Our argument on Dr. Baruch is a little bit different, and this is where we get to sort of the third level. If you have these minimum qualifications, and you have that something extra on being able to teach others how to make these judgments, then you look at what your methodology was in this particular case, and did you use an appropriate methodology?

We know from the Nease case that's a requirement to assess any expert's methodology, and that's where Dr. Baruch falls short here. He -- and I'll go to page 11, 12 and really on to 13 where we cite numerous instances of his deposition, of admissions from his deposition where he clearly hasn't done his homework in this particular case.

He may be qualified because of his experience and training and some of his background to generally speak as a labeling expert. But when he's asked about some of the specific details about FDA labeling requirements, or even the facts of this particular labeling history, he falls woefully

short. He's made mistakes in the historical background. He says he really hasn't spent a lot of time. He doesn't understand foreign labeling requirements. He didn't really investigate sort of the history of how the foreign labeling, ah, came into play and what the purpose of that was.

And so, yes, he came up with, you know, sort of a label himself. He doesn't really complete it. But I think the chief problem with Dr. Baruch is he hasn't done his homework here to really have an understanding as to what the labeling history here is and why the decisions were made, and that's just fundamental methodology. You gotta do your homework in order to offer opinions in front of a jury and try to persuade them that there was a bad label in this case. He hasn't done that.

So that's the sum and substance. I mean, otherwise, I guess, three labeling experts, we are sort of a little concerned about the duplicative nature and the cumulative effect of some of these experts as well. It seems to me they have Laura Plunkett also that is going to be talking about the label, and so the Court ought to consider whether or not three or four experts is really necessary on the label as well.

But that's the sum and substance of our labeling arguments, Your Honor.

THE COURT: Okay.

MR. LEWIS: The third bucket that we have here is

really this corporate intent, corporate knowledge, corporate behavior, and the law is pretty strong on this. Courts routinely prevent experts from offering or testifying about corporate mindset in product liability cases, medical device, pharmaceutical cases.

We cited a laundry list of other cases throughout our briefing that confirms that it is inappropriate to allow an expert to look at a series of documents, look at some documents or even read deposition testimony and say, you know, frankly, BI knew this or clearly voted for profits over safety or anything along those lines. Corporate intent, that's inappropriate for an expert. That's for the jury to conclude throughout the trial.

THE COURT: Do you perceive that plaintiffs are offering Plunkett to testify to more or different opinions than those considered by Judge Land in the Chambers case?

MR. LEWIS: I do.

It's a little murky as to what Judge Land's opinion is allowing Dr. Plunkett to testify about. I mean, it seems, when I read Judge Land's Chambers opinion, what he's really saying is that she could testify about warnings; in that way, what the company knew or maybe didn't know or should have known perhaps. I'm not sure Judge Land goes above and beyond and says, oh, and it can also draw conclusions about the corporate intent.

So I just -- when I read Judge Land's opinion, it sounds to me like he's really saying that her testimony is sort of relevant to warnings. At least that's the way I read it, the way he describes it, but it's a little unclear.

But, you know --

THE COURT: I think he noted that clearly she has a considerable amount of regulatory experience as to labeling. I know that he mentioned that in discussing the context of her use of these documents. And as I recall, he says she used the studies that the defendant had submitted to the FDA, and I guess even the ones perhaps done since then.

But you think plaintiffs are going further than something like that here?

MR. LEWIS: I really do because I've seen it so many other times.

THE COURT: Uh-huh.

MR. LEWIS: Dr. Plunkett is a well traveled plaintiff expert. And state of mind, motive, ethics, all of those things, if given the license, that's coming out. I mean, she's going to give a run at all of that if there's not some restriction put on her testimony, and I anticipate that the same thing will be done here.

And so really what we're looking for, Your Honor, is a decision that is sort of more in line with the cases we cite on page 12 of our reply brief, Seroquel, Pfizer. Even Judge

Land in that Mentor Obtape Transobturator litigation had an order related to that. That was my litigation, so I remember it.

THE COURT: And generally what those cases say is that you can certainly introduce documents from the defendant and reports, information about what they had. You just can't have the expert try to supply that last link to the inference that the plaintiffs are arguing just because they're an expert.

MR. LEWIS: That's exactly right. And that's what we're looking for here, is something consistent with what that body of law really says you can't do.

THE COURT: Great.

MR. LEWIS: All right. Thank you, Your Honor.

THE COURT: Thank you.

All right. For plaintiffs?

MR. CHILDERS: Your Honor, this is Neal Moskow on behalf of plaintiffs. He was not here at the last hearing.

THE COURT: Welcome.

MR. MOSKOW: Thank you, Your Honor. I appreciate the opportunity to appear before you.

Let me start by saying that my response to defendant's arguments is somewhat tempered by your May 31st order. I think a lot of these issues have already been addressed. I have a presentation, I'm certainly willing to start anywhere you want, but my gut instinct is to start right at the end of

Mr. Lewis's argument with regard to Dr. Plunkett.

THE COURT: Go ahead.

MR. MOSKOW: Because I happen to be the attorney who presented her in the first two state trials, in Connecticut in February and then again in March or April. And I assure you that if we had tried to offer some broad-based motive and intent evidence through Dr. Plunkett, whose ability to testify in Connecticut, because of the timing of how things worked out, was simply a denial of the -- we call it a Porter motion, but essentially it's a Daubert challenge. The court just denied it without a written opinion, so she had unfettered ability to testify.

And I assure you that if I or she had offered the testimony that Mr. Lewis has just suggested, you would have been presented with transcripts that would have shown it, and you haven't been. And the reason for that is simple, because that's not the plaintiff's intent.

What Dr. Plunkett does is she looks at what the company knew and how, if at all, that information is reflected in the warnings or other material provided to physicians. And what wasn't said in either the defendant's moving papers or here today is that while the FDA approved label is one indicia of whether the company has properly communicated information to physicians, in accordance with Wyeth versus Levine, it's just one indication. It's the floor of -- FDA regulations are

the floor and not the ceiling.

State law, in particular a state like West Virginia where the warning goes to the patient and not the physician, is a whole different paradigm from what the FDA regulations are considering.

So I think, you know, we heard a lot about fit, and we heard a lot about buckets, but what we really need to focus on are the facts of this case. And in the facts of this case, what Dr. Plunkett will do with regard to company documents, what Dr. Baruch will do with regard to company documents is say to the jury, this is information that we know the company had because it's in their own hand. And despite having this information, they didn't communicate it to physicians, and patients were at risk as a result.

A perfect example kind of brings us back to the first part of Mr. Lewis's argument regarding plasma concentration monitoring opinions. And that is that the company, for example, in its currently ongoing Diversity trial, which is using Pradaxa in children six months to 18 years of age, they have based their dosing regimen on a plasma concentration range of between 50 and 250 nanograms per milliliter. Which, as reflected in our reply papers, they chose because, according to the authors of that study, it was a level that had been proven to be safe and effective in multiple adult populations.

And in the paper that was just published on this art -- on this study, the footnote that they cite to for support is the RE-LY trial. That because of the evidence adduced during the RE-LY trial, they know that between 50 and 250 nanograms per milliliter is a safe and effective range.

And I think what has happened in the course of the various briefing that the defendants have done, Judge, is that they've tried to conflate two really distinct issues. There is a safe and effective therapeutic range, and there is an optimal range, and the two ranges are different things. That's why one is a therapeutic range, and one is an optimal range.

And if I could give you an analogy that I think might help kind of crystallize this for us. If you were driving on a highway, and you saw a sign that said speed limit 65, minimum speed 45, that is equivalent to a therapeutic range. You want to go at least 45 miles an hour so the 18-wheeler coming behind you doesn't strike you and hurt you. And you don't want to go over 65 because speed kills, and that's more dangerous. So we have a therapeutic range between 45 and 65.

Now if I'm driving a car pulling a trailer, I'm probably going to want to be closer to the 45. If I'm in a sports car, I would want to be closer to the 65. That is the optimal range. The optimal range is for an individual patient.

We're not talking about an optimal range should be in the label. What we're saying, and what our experts have opined, is that there should be a therapeutic range, this broad range that has been proven to be safe and effective in multiple adult populations.

Your Honor pointed out both in the summary judgment decision and then during argument just now that our experts have identified differing ranges at different times, as has Boehringer. In fact, you even cited in your order to the e-mail from Dr. Connolly where he says the range appears to be 40 to 200, and there's never a good reason to go above 200. That's one range. The Diversity study says 50 to 250. That's another range.

What our experts are saying is it was up to the company to identify the range that was most appropriate, it should be in the label, and then they should provide information as to how to test to see whether or not the particular patient is within that range. And then it's up to the doctor to decide for that individual patient, is this patient at a higher risk of stroke? Do I need to run them at the high end of the range? Is this patient at a high risk of bleed? Do I need to run them at the low end of the range?

That's the deficiency in the label. That's what each of Dr. Baruch, Dr. Plunkett and Dr. Chertow speak to in their opinions.

And if I may, I want to be very clear as it relates to Mr. Gosselin, whom you've identified as a research scientist. You know, he calls himself I think a lab guy. He does not ever opine or testify that he has ever made a clinical decision as to whether a particular patient should be on one anticoagulant or another. His expertise is squarely within the area of how one identifies whether a particular patient is appropriately anticoagulated.

And to the extent that he's providing any opinions in this case, those opinions go to whether the current label identifies appropriate testing and why or why not; and how, if at all, the label could be made better specifically with regard to that issue of testing.

And I think that distinction, again, gets kind of conflated into a bigger picture here. Well, he's not a doctor. Well, he isn't a doctor, and he makes no bones about it. But their Ph.D., Joanne Van Ryn, who is one of the leading scientists at the company -- in fact, she wrote the initial paper on dabigatran before it was on the market that set the tone for what Pradaxa is. She testified in her deposition that he's one of the top ten experts in the world on anticoagulation. So that's exactly the type of specialized knowledge that our expert brings to the table that the defendants ignore.

And I know I've kind of done a loop here to go from

the opinions regarding company documents, but I think it's important to understand in the context of what our experts are saying that each opinion is not only supported by internal company documents -- like the Diversity study or like e-mails between physicians at the company that say, yeah, monitoring might be useful, but it would put us at a competitive disadvantage versus Eliquis and Xarelto.

That kind of information supports the opinions, so it's not -- there was an argument a few moments ago that Dr. Baruch didn't understand how a particular test worked or didn't understand how a particular model worked. It's not required that he understand how it works. What he has to -- what he understands and what he testified to is that, based on the modeling, he was able to identify patients who were at higher risk of bleeding.

And you know what --

THE COURT: Well, and he's relying upon the conclusions of the model to do that?

MR. MOSKOW: He is to a certain extent, Judge, but that conclusion is published in the medical literature authored by the defendant's own employees.

Dr. Reilly and Dr. Lehr published the dabigatran concentration paper in the Journal of American Cardiology, and that paper specifically states that there is a point at which there is minimal, if any, additional benefit from increasing

plasma concentrations while there is significant increase in bleeding risk. So his opinions are borne out by the medical literature.

Whether he knows whether it's a regressive model versus an exponential model is of little consequence when it is used in the grander picture here where he knows that increasing concentration is tied to bleed risk. That information is not in the label. And the company's own research demonstrates that there is a sweet spot at which you maintain stroke protection efficacy while minimizing bleed risk.

I want to, if I could, go back to this issue of fit that Mr. Lewis started with, Your Honor.

Much of the argument that you've heard talked about how these opinions relate directly to Ms. Knight's treatment. I want to make clear that the experts that we're here talking about today, Drs. Plunkett, Baruch and Chertow and Mr. Gosselin are all generic experts. They're not going to be talking about the specific, ah, interplay between their opinions and Ms. Knight. In fact, they have not been disclosed to do so.

What they will do is they will set the stage for someone like Dr. Huff, who you've already -- Dr. Ashhab, I'm sorry, who you have already indicated can testify to these issues. So what they'll do is they'll set the stage for the

jury. They'll explain where the science comes from, how it fits in, and then Dr. Ashhab will be in a position to explain how that information, had it been available, would have directly impacted Ms. Knight.

That's the fit, and I think that's an important distinction.

THE COURT: Can you answer the question raised by the defense in sort of the opening discussion on the monitoring? And that is, what precisely is plaintiff's theory, and what do you expect to adduce from in particular Dr. Baruch? You expect him to testify about a particular range and say that's the range that should have been in the label or something or what?

MR. MOSKOW: Thank you, Your Honor.

What I would expect Dr. Baruch to testify to is that the company has identified several different ranges. They have access to all of the data, and they're the ones who have been conducting the analyses over the last eight years, and it's up to them to identify what the appropriate range is.

I believe what he testified to at his deposition in a couple of different ways is -- and I actually wrote it down, is that for a particular type of patient, you may want to run them higher or lower. But there is an overall appropriate range and, you know, whether that is again the Diversity range of 50 to 250, or the Connolly range of 40 to 200 and

something, you know, that the parties haven't really had an opportunity to get into a lot of detail with you, Judge.

But what the jury will likely hear is that there were a series of drafts of the Reilly Lehr concentration paper between 2011 and 2013, and that early drafts included a therapeutic range that settled at 40 to 200. And that there was a decision by management at the company that the paper could not be published with that therapeutic range in it, and it had to be removed, and that the focus of the paper had to change from plasma concentration range to patient characteristics, and it did.

And a significant portion of the company documents that Dr. Plunkett will talk to the jury about will be that interplay between management and the scientists and the physicians, in which they identify a therapeutic range that would make the drug safer while maintaining its efficacy and yet, for business reasons, have chosen not to do so. And that's why it's hard to argue -- excuse me -- it's hard to argue any one of these opinions in a vacuum. They really fit together like a puzzle.

And the puzzle pieces here that get put together reflect a company decision before the RE-LY trial even commenced that this would be a drug that would not require monitoring or dose adjustment. The trial was designed that way. The drug was approved that way. And, you know, damn the

torpedoes if there is any evidence that suggests otherwise, we're going to ignore it. Or in the case of two of their lead physicians in this case, Dr. Friedman and Dr. Heinrich Nols, they were seeking changes in the manuscript to avoid that issue becoming public.

So the point that Dr. Plunkett, Dr. Chertow, Dr. Baruch will all testify to is that there is a therapeutic range. The company has a duty to identify it. And then, after it's identified, it has a duty to instruct on what testing should be used in order to appropriately determine whether a patient is within that therapeutic range or not.

And contrary to this argument both in the summary judgment papers and in the papers regarding Daubert, that there is no fit here because the 75-milligram dose is the lowest dose, that's ridiculous. If the patient is outside this therapeutic range, is overly anticoagulated, then the appropriate course would be to switch therapies.

And with Ms. Knight, she was on Warfarin before without a bleed and without a stroke, so we know that that's a therapy that could have been appropriate for her.

And I think what's significant, Your Honor, is that in the label, in Section 2.2, in the situation in which a patient develops renal failure while on the drug, the company says discontinue Pradaxa in patients who develop acute renal failure while on Pradaxa and consider alternative

anticoagulation therapy.

So the label that is at issue here recognizes that for some people this is not the appropriate drug. They just don't want it broadcast that it's more people than have just suffered renal failure. And how do we know that? We know that because, as the Court has already found, the 10th to 90th percentile reflected a huge range, and there are people outside that range who are either under-coagulated or over-anticoagulated. So, again, the opinions coalesce around that issue.

And with specific regard to Dr. Chertow, I just want to point out not only is he an endowed professor at Stanford, so talking about he doesn't teach things to people kind of -- maybe I misunderstood the argument. But this is somebody who taught at Harvard, at University of California, San Francisco, and now at Stanford. He's chief of nephrology and an endowed professor at Stanford.

He has published more than 500 peer-reviewed articles regarding kidney and kidney function. He's the author and editor of the textbook called The Kidney. He's currently involved in an investigator-sponsored trial concerning the safety of Eliquis, an anticoagulant.

And significantly what he has written about in his report, what he testified to at his deposition, what we anticipate he will testify to at trial is that small

degradations in kidney function have a significant impact on increase in plasma concentration. And that a patient who is at 40 or 35 or 30, or let's call it 31, doesn't just suddenly require a different dose when they hit 30. That there are clinical characteristics, there are clinical findings that together with a reduced kidney function may make it appropriate for a patient to be on a different dose or a different therapy. And that opinion is confirmed in the European label.

In the European label, somebody who has 50 -- a creatinine clearance of 50 and is on a P-gp inhibitor, like Ms. Knight was, the label says consider a lower dose. Take an anticoagulation test, determine whether or not your person is appropriately anticoagulated, and consider a lower dose. They don't say that here.

Now the argument has been from time to time that the reason they don't say that here is because the FDA didn't approve the 110 dose. Well, then the label could just as easily say to determine whether or not the 150-milligram dose is too much for this particular patient. It doesn't have to be -- drop to another dose. It could say if this dose is too much, there's another therapy.

And that's essentially Dr. Chertow's position here, which is that when you have a patient population that is -- that skews elderly, they have reduced kidney function, you

take a drug like Pradaxa that is predominantly cleared by the kidney, as much as 80 percent, and you have somebody who has even small degradation in kidney function, you can expect this huge increase in plasma concentration.

The same is not true with Eliquis or Warfarin. It's -- to a lesser extent, it's not true with Xarelto either. Xarelto is around 50 percent kidney cleared. So his specialized knowledge goes directly to the issue of whether the information conveyed in the U.S. label is sufficient to advise physicians as to how to appropriately dose their patients.

I know I have bounced all over, Your Honor. I did want to say --

THE COURT: I did want to give you a chance to -- I don't know if you had a chance to look at this during argument, but Mr. Lewis asked me to look at, with respect to Mr. Gosselin, pages 118 and 119 of his deposition testimony where he's discussing his --

MR. MOSKOW: His qualifications.

THE COURT: -- experience.

MR. MOSKOW: Yes, his experience.

I don't want to in any way mislead the Court. Mr. Gosselin -- and I spent the last trial calling him Dr. Gosselin, and Judge Morgan kept having to correct me, it's Mr. Gosselin, after she allowed him to testify.

But he's not testifying as to whether or not this particular information was necessary to evaluate a particular risk. What he testifies to is that in order to know whether or not the patient is appropriately anticoagulated, you need to test. The aPTT test that is reflected in the label is insufficient for that purpose for a variety of reasons, including the lack of identification of the reagent so you know what the appropriate range or effect is. But he also indicates what are appropriate tests and what information could be in the label that would allow physicians to identify what their patient's particular anticoagulant activity is.

So his opinion is really focused on the testing that is in the label and what should be in the label. I think it's a qualitatively different opinion than what Drs. Baruch and Chertow and Plunkett are opining on.

THE COURT: All right. Thank you.

MR. MOSKOW: Your Honor, unless you have any further questions, the only point I would make about Dr. Gosselin is that he's been talking and teaching about anticoagulants and how to test for them for 30 years, and he's exactly the type of expert who can provide the jury with information that is not in the common lexicon as to how one identifies whether a patient is properly anticoagulated.

And at the end of the day, that is really what Judge Land found for each one of these experts, that to the extent

that there are any issues with prior testimony or whether they understood how a particular model worked or whether they considered all of the company documents, each one of those things goes to weight and not admissibility. That their opinions are consistent with scientists in their field, they're reliable to the extent that they rest on company data and peer-reviewed medical journals, and that each one of these experts has particular expertise in the areas in which they're offering testimony.

THE COURT: All right. Thank you.

MR. MOSKOW: Thank you, Your Honor.

THE COURT: Mr. Lewis, I will give you just a few minutes of rebuttal.

MR. LEWIS: Very briefly, Your Honor. Thank you.

THE COURT: Hold on just a second.

MR. LEWIS: Sure.

THE COURT: Go ahead.

MR. LEWIS: Thank you, Your Honor, a few quick points, number one just about the reliance on Judge Land's Chambers decision.

And I have a lot of respect for Judge Land. I've been in front of him for ten years in a completely different litigation, so this isn't a criticism of Judge Land in any way. But with all due respect, I'm not sure that Chambers opinion would stand scrutiny under the Fourth Circuit from the

Nease decision. I just think that this idea of putting everything to cross-examination and to weight and not doing a full analysis under Daubert, at least in this circuit, is a dangerous thing for a district court judge to do. It seems like the Fourth Circuit wants the Court to go a little bit further than Judge Land did. So that's just kind of a first blush argument.

Secondly, I wanted to briefly address Dr. Plunkett and something that is in her report. We cite to this in our brief. But one of the conclusions that she reaches in her report, just so the Court has an example of where she'll go, is that Boehringer Ingelheim's decisions, based on a bunch of facts and documents and things, were driven by economic concerns and competitive advantage. So that's just an example of the type of conclusion that is not permitted and should not be permitted.

And that's --

THE COURT: You would have no quarrel, I assume, if Dr. Plunkett was presented with a document -- plaintiffs have cited these two or three times -- where there is some reference in e-mails or other documents where someone from the defendant says, well, we don't want to publish that or that would hurt our competitive advantage.

So I assume you understand those are documents that are going to come in.

MR. LEWIS: They're coming in.

THE COURT: But you just don't think the expert ought to be able to offer an expert opinion that documents like that, even statements like that form -- are evidence of some corporate intent that the expert's going to identify?

MR. LEWIS: Correct. Exactly right, Your Honor. Because an e-mail doesn't prove an overall corporate intent. I mean, it just doesn't.

I mean --

THE COURT: Well, I think, you know, part of the difficulty with things like this and issues like this before the Court is, you know, I don't have specific testimony or anything. I don't think I have any difficulty saying that if this case goes to trial, that if Dr. Plunkett or other plaintiff experts attempt to gather a series of defendant statements and say, based upon all these, my opinion is that this defendant was trying to hide the truth about Pradaxa just to make money, we're not going to let that type of evidence come in. That's not within the realm of expertise of any of these experts.

But they certainly can say, and Dr. Plunkett I think is a good example -- she might be sort of a steady regular plaintiff's expert, but be that as it may, she certainly has expertise in the FDA process for her to be able to say these are the documents that the company had, and they either were

or weren't part of the FDA approval. She can testify to those things.

MR. LEWIS: I think that's fair land.

What we're looking for in this motion practice pretrial is some guidance from the Court so we know how to frame the case, and we're not jumping up in the middle of trial here and there. I think both parties could use a little guidance --

THE COURT: Okay.

MR. LEWIS: -- from the Court.

Let me just address real briefly also this monitoring, this plasma monitoring issue one last time.

So I focused a lot on fit in my opening. In our briefing, we also talk about reliability. And that is a similar, but a little bit different animal, reliability than fit in a particular case. And under the Nease decision, it's an analysis that needs to be done.

So I heard plaintiff's theory. It doesn't appear that they're actually going to cite a number, 50 to 200, or 35 -- it doesn't appear that they're going to say a range. They are going to say, hey, the company thought about a whole bunch of ranges, and they should have put in their label that you should do some plasma monitoring. And maybe they should have given a range or maybe they shouldn't have, who knows.

When we talk about reliability, we're talking about,

okay, that's your theory that a different label would have made a difference, generally speaking. But there are no studies to suggest -- and you'd think they might have some data on this given that there is a European label that is different from the U.S. There's no data to suggest that putting monitoring in the label actually changes clinical outcomes for patients.

I mean, there's no data to suggest -- in fact, the more recent data that has been published is that monitoring really doesn't matter. You'd think we would have studies out there that would show that, oh, for this patient population with a label as X, we end up with outcomes of far fewer bleeds or the stroke risk is, you know, the same or what have you. We don't have that kind of information. That's what we mean by reliability. Are you testing the theory that a different label generally would matter?

And then let me talk about fit again one last time.

So imagine in this particular case, the plaintiffs have no theory on what the range should have been provided to physicians, just some range should have been provided. Well, if the plaintiff actually in this case would have fallen within a range that would have required no action by the physician based on whatever we published in the label, then that whole theory doesn't fit this case. It can't lead to liability in this case.

To give you an example in a completely different context, let's just talk about a product case. It's the difference between saying -- okay.

Let's say it's a defective tire case. Plaintiff comes in, has an accident with a tire and says you should have made your tire differently. That's it, that's really all they're doing here is saying you should have made your tire differently. But what the law requires is you gotta do more than that. You gotta say, well, wait a minute, how should we have made our tire differently, number one? And if we had made our tire differently, would that have avoided the accident here, number two?

Daubert requires that two-step analysis, what should have been different, and would it have mattered in this particular case. Here the plaintiffs do not have that evidence connected up to say, oh, if you had changed your label to put something in there about monitoring, Ms. Knight would have never suffered this bleed event.

THE COURT: Well, they've got Dr. Ashhab, whose testimony will be that she was over-anticoagulated, and that Pradaxa contributed to that over-anticoagulation, and that's what caused or contributed to her major bleed. So if he's supplying that causation evidence, why do the plaintiff's general experts have to testify that having monitoring would have made a difference?

Dr. Ashhab, and we won't go into the others, but to a lesser degree the others, they're all saying she was over-anticoagulated. And if we had known as treating physicians how to monitor, and that we should monitor when we've got a patient with these characteristics and this combination of medications, then monitoring would have revealed her over-anticoagulation.

MR. LEWIS: And my question is, Your Honor, then what? Then what would you have actually done differently with this particular plaintiff? And that differently thing -- that different thing that you would have done, how would that have led to a different clinical outcome?

There's the analytical --

THE COURT: Well, their evidence was that given this host of problems, that had she or her doctors been fully aware of all this evidence the plaintiffs now claim and had been fully informed of that through the kind of labeling and patient medication guide that plaintiffs are arguing, they more likely than not would have recognized she was over-anticoagulated. And if at that point there is no information available to them for any different dosing, they would have just put her back on Warfarin where she hadn't had a bleed, even though she had the challenge of being monitored and all that, which is what she was trying to avoid.

But it seems to me that they've got enough evidence

that that should be for the jury to determine, and that the plaintiff's general experts don't have to supply all of these elements. They only have to -- all they're being offered for is that general causation basically, and that it's the specific causation evidence of the local doctors that fills the gap and completes at least the prima facie case.

MR. LEWIS: And, Your Honor, with all due respect, the way that you articulated the specific causation piece of this is not actually what is in the record. Again, with all due respect, the only testimony that is in the record is that it would have been considered. And it's that -- and Your Honor put it very well because it actually proves why these folks shouldn't be able to testify.

If there was testimony in the record, if Dr. MacFarland came in and testified in her deposition, you know what, having known about this and her range would have been X, I would have definitely put her back on Warfarin -- that's not the testimony. That is -- no doctor has testified to that. Not even Dr. Ashhab goes that far.

Dr. Ashhab does not even say what should have been done differently. He just draws the conclusion that she was -- and, again, we take issue with this. We think that's wrong. But he draws the conclusion that she was over-anticoagulated. He doesn't say what should have been done differently.

And, again, if the -- and I respect the Court's decision on summary judgment, the jury can hear that, the Court has allowed that testimony in. But to allow these generals to come in should not be permitted because it really doesn't satisfy that Daubert threshold to connect it up.

THE COURT: Okay.

MR. LEWIS: Thank you, Your Honor.

THE COURT: Thank you.

All right. Let's turn to the plaintiff's omnibus motion in limine.

It looked to me like there were -- I guess you raised three different issues or areas. Obviously I think the first two can be dealt with fairly quickly.

MR. CHILDERS: Yes. Andy Childers on behalf of plaintiff. And I don't intend to spend a lot of time arguing these. I think they are fairly straightforward and in the record.

The first is to prevent defendant from coming in and soliciting information about their good acts or good deeds that they do either in the community or by making other drugs that are different from Pradaxa and what have you. I think it's fairly straightforward under Federal Rule of Evidence 403 that that's not permitted.

And if it was, if that information did come in, the company has done some really bad stuff, too. We don't have

any intention of coming in here and pointing out that they hired a convicted Nazi war criminal. But if they were allowed to talk about the good acts, we think that would open the door.

THE COURT: Well, let me make two observations, and you can react to that, and we'll hear the defense reaction to it.

First, I generally agree with the proposition that the company can't come in and just offer the portrayal of its good conduct, good reputation that is not connected to Pradaxa. I think they're entitled to, as I would summarize it, introduce themselves to the jury. I have no real difficulty with the defendant describing its corporate makeup. Apparently it's a privately held family corporation. I think they can put that in. I suppose they can testify or offer evidence about the size and location of the corporation, where they do business, where they make things, where they sell things. So things like that I don't have any trouble with.

With respect to its development of Pradaxa, I think they're entitled to introduce evidence about the reason that they thought it was important to develop a drug like this, what they were responding to, the legitimacy of developing a drug that is at least arguably a preferred or a better option than other more traditional blood thinners.

I think they can offer evidence about how much they

spent developing that drug, all of the steps they went through, all of the -- a description of the whole process of approval and the studies and all those sort of things.

I think they cannot start to offer evidence of how their aim is always to produce the very safest drug no matter which drug it is they're producing or statements like that as to their purpose or intent outside of their development and marketing and sale of Pradaxa.

So if that is the way they're restricted, do you see a reason to challenge it?

MR. CHILDERS: No, Your Honor.

THE COURT: Okay.

MR. CHILDERS: That's all we're trying to do, is sort of keep it inside those boundaries as well.

THE COURT: Okay.

MR. CHILDERS: The second issue we have is a very -- I thought a very concise issue that I think maybe the defendants misunderstood as being more broad.

We've had several depositions where defendants refer to the United States label as the FDA label or the FDA's label, and the case law couldn't be more clear from Wyeth versus Levine. The FDA doesn't draft and is not responsible for drug labels. This is Boehringer's U.S. label for Pradaxa. And all we are seeking to do is prevent Boehringer from coming in and trying to assert to the jury that the FDA somehow

created this label, or this is the FDA's label as opposed to their label. The case law is clear from the Supreme Court of the United States. That's not accurate, and that's solely what we're trying to prevent here.

THE COURT: Well, again, at least through Dr. Plunkett but perhaps through other witnesses, too, you're going to be describing what the company knew, what it submitted to the FDA, how the FDA responded, how the whole label evolved into what was ultimately approved by the FDA. So honestly I think with the way the evidence is going to come in, I certainly don't intend to let the defendant argue that they were prohibited from any other type of label. Rather, I think the evidence is clear that they submit a label to the FDA for approval, and in that context it's the FDA approved label.

MR. CHILDERS: Right.

THE COURT: And the connotation of that is no more than this is what the company developed and presented and the FDA found adequate at the time and approved. And so as long as that is the context of this discussion -- and I'm not going to interrupt them every time they refer to the FDA approved label to distinguish it from, you know, some other version or characterization of the label.

MR. CHILDERS: And, Your Honor, I think saying the FDA approved label, I don't have -- I don't have a proper objection to that frankly because they did approve it.

My concern is sometimes they call it the FDA label, and --

THE COURT: Well, I understand what you're saying. You know, I think that that's -- given what I think the evidence is going to be, I don't think that nuance is going to confuse the jury. I don't think that is going to allow them to argue or lead the jury to conclude that somehow this label is not the responsibility of the defendant but, rather, this is what the federal government did or something to that effect.

MR. CHILDERS: I think you may be surprised when we go through this trial, Your Honor.

THE COURT: That could be. But I certainly intend to make sure the jury understands the evidence and is properly instructed to understand the process by which the FDA approves a label and what that means, whatever you want to call it, the FDA approved label or an FDA label or whatever else.

MR. CHILDERS: Fair enough, Your Honor.

THE COURT: Okay.

MR. CHILDERS: The final issue that we had in our omnibus motions in limine is to preclude the defendant from arguing that the FDA has made a conclusion with regard to whether or not titrating or changing the dose of Pradaxa based on a patient's blood level is or is not appropriate. This -- we've had two trials thus far, and in both trials they've

attempted to argue that to the jury.

There is no evidence --

THE COURT: Has that all just been from Dr. Mann?

MR. CHILDERS: No, Dr. Mann hasn't come into trial.

THE COURT: All right.

MR. CHILDERS: It's been -- this was filed before --

THE COURT: Okay.

MR. CHILDERS: -- I believe we got to that point.

So what happens is they come in and say that we gave to the FDA information we gave to the EMA, and that the EMA responded, the EMA being the European Medicines Agency, related to the therapeutic dose. The therapeutic dosing, excuse me, Your Honor. And when we gave it to the FDA, they decided we didn't need to include that in our label in the U.S.

Well, the problem with that, I think as Your Honor understands with the way the drug label is approved and then whose responsibility it is, the company has never submitted to FDA a drug label in which they've asked the FDA to reject or approve the use of adjusting the dose based on blood level of the patient.

THE COURT: You know, I understand it. How did we get a 110 dose?

MR. CHILDERS: In the United States or in the rest of the world?

THE COURT: In the United States.

MR. CHILDERS: Through a different indication -- excuse me, Your Honor -- for use in orthopedic --

THE COURT: How did that come about?

MR. CHILDERS: They applied for it for those purposes, ah --

THE COURT: So this wasn't something where the FDA said, all right, we've seen your RE-LY study and all of these things, and you've proposed a 150 dose for a whole bunch of different conditions or situations, and as we look at this, we really think maybe you ought to do a 110 dose for certain patients.

And so --

MR. CHILDERS: I may need to back up a bit.

THE COURT: Okay. Go ahead.

MR. CHILDERS: It was kind of the opposite.

THE COURT: All right.

MR. CHILDERS: They came to the FDA and asked the FDA to approve the 150 and the 110 dose at the same time for atrial fibrillation specifically. The FDA said, no, we'll only approve the 150, but we will let you make a 75-milligram dose for patients who have severe kidney impairment, different from the rest of the world.

THE COURT: Okay.

MR. CHILDERS: So it's sort of a separate issue. They

have -- they have now gotten the 110 dose approved in the United States, but not for atrial fibrillation. It is approved for other uses outside of that.

One of the issues that is not at issue in this case, but was in some of the other cases, is whether or not the evidence of why the 110 dose has never been approved in the United States for atrial fibrillation, why that is. The company has been told by FDA, there are certain things we want you to do if you want to get it approved, and they haven't done it. That hasn't come into evidence in any of the first two trials. It's really not an issue here because the 110 dose isn't really at issue anyway.

THE COURT: Yeah.

MR. CHILDERS: The issue that we have is the information that was developed internally by Dr. Lehr, who we're going to talk about a lot in the spoilation motion as well, that a patient could be put on the 150-milligram dose, and if it was too high when they measured it, it could be switched to the 75-milligram dose, didn't have to have a 110-milligram dose. And that in doing that, they would lower the amount of bleeding that would occur, but they would maintain the safe -- the stroke prevention efficacy of the drug.

That information has never been proposed by the company to be included in the label, and so FDA has never made

a decision saying, yes, we do think you should do that or, no, we don't think that's a good idea. FDA hasn't said one way or the other any official position because the only way they can give an official position is if the company proposes a label change to them.

I expect, because I've watched it happen twice, that Boehringer will come to this courtroom and say we gave all this information to FDA, and they made a decision that that should not be included in the label.

THE COURT: We're talking now about the monitoring --

MR. CHILDERS: Yes, sir. Yes, sir. About measure the plasma concentration in the individual patient, and if it's too high, lower the dose; if it's too low, raise the dose. That's never been proposed as a part of a label change ever in the United States.

And so the implication is that the jury is going to be led to believe that was proposed to FDA when it wasn't. And what we're simply seeking is that because there's no evidence that ever happened, that we preclude -- that the defendant be precluded from making an argument that it did.

That's pretty much it.

THE COURT: Well, and so what I've had trouble grasping is what this means in practical terms when the defense presents its case.

So you're going to present evidence in your case of, I

assume, RE-LY and some of these other studies and the sort of underlying clinical data that would support determining that the company should have proposed a monitoring system and determine what -- how to monitor and what range to look for.

And so the defense is certainly going to be able to offer evidence about what it submitted and have its doctors and its experts explain that these things don't suggest that monitoring --

MR. CHILDERS: Certainly.

THE COURT: -- should be required.

So I assume you have no trouble with that.

MR. CHILDERS: No. And --

THE COURT: You just don't want the argument then that the defendant would make that the FDA, in approving the label, disapproved implicitly at least monitoring and dosing titration.

MR. CHILDERS: That's correct.

And I expect them to come in and say there's a good reason why we don't monitor this drug. We're going to have people say that.

THE COURT: Right.

MR. CHILDERS: What is not proper is for them to say FDA has concluded that as well, because there is no evidence that FDA has been presented that information to be considered and then made any conclusion. That's the issue, that sole

issue.

Certainly I believe they can come in here and tell the jury here is some literature, here is what our scientists say --

THE COURT: And I won't pretend to have a grasp of the FDA process and certainly not the terminology. But my recollection I think from reading Dr. Mann's report is that there's a formal step, and perhaps that's the investigational drug proposal or something like that, that there is a formal step that FDA recognizes as being the formal step requesting approval of a drug.

MR. CHILDERS: That's called the new drug application, Your Honor.

THE COURT: The new drug application.

And so, in your view then, they would have to produce a new drug application or something akin to that or a modified label and approved usage.

MR. CHILDERS: Yes, Your Honor.

Once -- if I could, and I don't want to belabor this, but the new drug application is to get the drug approved with the initial label.

THE COURT: Right.

MR. CHILDERS: After that, they can change the label using what's called a changes being effected, CBE.

THE COURT: Right.

MR. CHILDERS: Or they can ask for supplemental -- or excuse me -- for a prior approval of a change to the particular label. What we're saying is without submitting a CBE or a prior approval application, the FDA doesn't consider whether or not anything should be added to the label.

And that is the only thing we are seeking to have precluded here, is to not allow the company to come in and say, well, because we went to a seminar where there was an FDA person there, and they spoke about it, somehow the FDA has made a decision, a conclusion that what the plaintiffs are saying is just not right. That's -- it's never happened, and that's all that we're asking the Court to preclude.

THE COURT: All right. Thank you.

MR. CHILDERS: Thank you, Your Honor.

Any other questions?

THE COURT: No, sir.

MR. CHILDERS: Thank you.

THE COURT: Mr. Lewis, are you responding?

MR. LEWIS: Yes, Your Honor.

THE COURT: All right.

MR. LEWIS: Again, thank you for the opportunity, Judge.

I really don't have anything to say on the so-called good company argument.

THE COURT: All right.

MR. LEWIS: I think Your Honor has tackled that.

On the FDA label comment, again not much to say there except, you know, I think in maybe some of the video depositions or whatever, folks have said FDA label, but the jury is not going to be confused.

It's --

THE COURT: I'm not troubled about that. I would only be concerned if through a witness or through arguments or statements by counsel that it might -- if I heard something that I think might be misinterpreted by the jury to contradict what we've described as being the process, only then would I believe it necessary to --

MR. LEWIS: Fix it or --

THE COURT: Yeah.

MR. LEWIS: Okay. On this third issue, just a few points.

Your Honor, what we've done in the prior trials and what we intend to do in this trial is just talk about the facts. The facts are that the FDA has to approve our labeling. And the facts are that we submitted a whole bunch of evidence to the FDA related to plasma monitoring, and the facts are that the FDA has never said to us you need to put that in your label.

THE COURT: Well, but you've never proposed to the FDA that that be the case.

MR. LEWIS: There has never been a label proposal to the FDA, and we're not going to argue that we have.

THE COURT: I think I would have a lot of trouble with the defendant arguing at trial that we gave all this information to the FDA, and included in that information is all of the underlying data and the studies, and also included are all these discussions by clinicians or doctors or even some of the medical literature that discusses plasma concentration and monitoring and, you know, how you could do it or how you don't need to do it or whatever.

If you didn't ask the FDA to approve a label or the drug itself originally with monitoring, I don't think I'm going to let you imply to the jury that the FDA has somehow disallowed monitoring.

MR. LEWIS: We're not going to say the FDA disallowed monitoring. We're not intending to say that it rejected a label change.

THE COURT: Okay.

MR. LEWIS: But we want to talk about the facts of what was submitted to the FDA and what actually occurred.

I mean, we have -- we cited --

THE COURT: Well, I don't have realtime up here, but what was it you first said when you started your argument just now? You said something to the effect that you want to be able to show and argue that the FDA did not approve a

monitoring requirement or label.

MR. LEWIS: The FDA, with knowledge of the information that we submitted to the FDA, did not require us, did not require us to include that information in the label. That's a fact.

THE COURT: Boy, I don't -- I think that is -- I want to think about it, but I think that's a mischaracterization then of what the FDA did and wrongfully implies that the FDA considered and made an affirmative decision to not require monitoring. I don't think that you can say that if it's not part of your proposal, that the FDA decided it.

MR. LEWIS: Let me just point out two things, Your Honor.

On page 10 of our reply brief, we cite Cardiac Safety Research Consortium, a paper that was published in 2018. The authors are four FDA folks on that paper.

THE COURT: Right.

MR. LEWIS: And that paper concluded that routine PK-PD measurements to guide the dosing cannot currently be recommended due to the lack of reliable tests, lack of clinical evidence of benefit and data to guide the appropriate dosing.

THE COURT: That should come in.

MR. LEWIS: Right.

THE COURT: I think that's different, admitting that

as evidence is different from saying that the FDA did not require you to include monitoring in the label and using that to imply that somehow the FDA actually did consider and determine that you shouldn't include that in the label.

MR. LEWIS: And let me explain why it's a distinction without a difference, but it's an important --

THE COURT: Okay.

MR. LEWIS: -- it's an important argument for us in this case.

Because we have the specter of punitive damages in this case, right? So the plaintiffs are arguing that because of our conduct in not including plasma monitoring on our label, among other things, but because of our conduct in doing so, we acted maliciously. Punitive damages should be awarded against us for that. And we want to be able to argue, first of all, look at all the facts, and we'll just speak of the facts as the facts. This is a paper that was published. It had an impact on us.

The information that we supplied to the FDA over time about plasma monitoring, and the fact that the FDA didn't say -- didn't call us up and say, hey, you actually -- we've seen your information, you need to change this, you need to put this in your label; or, hey, we know that Europe is requiring certain things in the label, we want you to do the same thing as Europe; that is impact -- that is important for

us to be able to tell the jury --

THE COURT: I don't think this -- I don't think my sense of where to draw the line keeps you from offering evidence of those facts.

MR. LEWIS: Okay. All right. Then I don't think there's a big difference.

THE COURT: Okay. Maybe there's not. You know, this is one of those where we'll just have to wait and see how this sort of comes out of trial.

MR. LEWIS: Well --

THE COURT: You know, like the --

MR. LEWIS: And honestly, Your Honor, I think that's the better course, is to -- whatever guidance the Court provides to give us a shot to -- as the trial develops, to talk to you more about it if we can.

THE COURT: Right.

MR. LEWIS: Okay. Thank you, Your Honor.

MR. IMBROSCIO: If I may, Your Honor.

There is just one legal -- good afternoon, Michael Imbroscio.

One legal difference actually that follows, I believe, is in 2007 Congress passed what's called the FDAAA, FDA and two extra As. In that, they codified what is now Section 35504, which is a new provision that post-dated the facts in Wyeth versus Levine. What that provision says, it puts an

obligation on the FDA that if they are aware of a safety issue that should be in the label, then they have an affirmative statutory obligation to raise it with the sponsor, with the drug manufacturer, and to come up with labeling. And if the sponsor does not agree, the FDA has the right to impose that labeling.

That's a different regime than what existed in Wyeth versus Levine. There's a footnote in Wyeth versus Levine that says this case pre-dates this provision, it doesn't address it. And I think that in many ways changes the calculus at least enough to what Your Honor is getting at. The fact that the FDA had all of this information. The fact that in 2010 the FDA scientist testified publicly around the approval of the medicine that we looked at the issue of monitoring and we don't think it's appropriate. That's from his public testimony at the approval hearings. There are subsequent interactions with FDA folks, including in the two meetings involving a CSRC ultimately published with FDA authors, that concludes there is not enough to recommend monitoring.

And so we're certainly not going to say the FDA rejected a monitoring proposal, but we think those facts as facts should come in, and it's not an answer to say that the FDA did not have any obligations to suggest or impose a monitoring regime if the FDA thought that was the appropriate step. That's what 35504 says.

THE COURT: Okay. I'll think about that.

MR. IMBROSCIO: Sure, Your Honor. Thank you.

THE COURT: Do you want to respond to that?

MR. CHILDERS: Just to that one issue, if I could.

The change in the CFR that gives the FDA certain powers doesn't have anything to do with whether or not the FDA has actually made a conclusion in this case about whether or not plasma monitoring is or is not appropriate. The FDA would have to actually opine that. And the whole issue we have here is there is no opinion from the FDA because there has never been a vehicle for the FDA to do that.

There is -- to say the FDA has made a decision about that, they base that on two things. One is the CSRC paper which, I agree, that paper is going to come into evidence. The fact that some of the authors work at FDA does not make that an FDA proclamation or conclusion. Some of the other authors are employees of Boehringer Ingelheim and doctors from other parts of the country and the world.

And that paper also says very specifically Pradaxa, unlike the other NOACs, the other drugs on the market, has a sweet spot between 50 and 150 nanograms per milliliter where the safety and efficacy seem to be greatest, but the company hasn't done enough testing on it for us to recommend it. That's what it says. So why has that not been recommended? Because they haven't done the testing.

The other issue that he brought up was the 2010 testimony at an advisory committee hearing from one employee from the FDA. Again, that's not a decision by the FDA. That's not even where the drug was approved. The drug was approved a month later by a different panel of people.

So what they try to do -- and I can tell you this because I've watched it happen twice. They will take those two things, and they will present it to the jury as saying this is what the FDA has decided, and that is something the jury will believe even though it's not true.

THE COURT: Well, I thought you told me before that the jury had found the product defective in both those cases.

MR. CHILDERS: They found -- they found in the first case that there was failure to warn and in the second case failure to test.

I can't tell you because I wasn't in the jury room, but I can tell you it's very powerful for a company to stand up, a drug company especially -- because the jury has no idea how involved the FDA is. And believe me, in a two- or three-week period of time, we can't explain to them everything we know about how limited the FDA's powers really are. They think if the FDA has approved a drug, if the FDA has made a decision, well, it's probably absolutely right, and then the plaintiff has a huge uphill battle to get past it.

So the only issue that I would -- or I would just urge

Your Honor, when considering this issue, to look at what they're trying to rely on for evidence of FDA making a decision. Because the FDA has never made such a decision, and to allow them to say that would just be improper.

Thank you, Your Honor.

THE COURT: Thank you.

Let's turn to the spoilation, and you have filed cross motions about this. It's the plaintiffs who seeks to offer this evidence at trial, so I'd like to have the argument presented by plaintiffs and then responded to by defendants.

MR. CHILDERS: Thank you, Your Honor.

Can we just argue these together? Is that how you want us to do it?

THE COURT: Yes.

MR. CHILDERS: Okay. Super.

THE COURT: And the simplest way would be to try to tell me, succinctly if possible, what specific evidence of spoilation you're relying upon --

MR. CHILDERS: Understood.

THE COURT: -- and what -- yeah.

MR. CHILDERS: Understood.

I could boil it down into two custodians in particular, the first being Dr. Lehr. Sometimes he is called Professor Lehr.

THE COURT: Right.

MR. CHILDERS: And I think he is now called Professor Dr. Lehr. That is a title in Germany when you reach a certain level.

Dr. Lehr was a research scientist at Boehringer, he was intimately involved in Pradaxa, and he was the person who did the modeling that made the determination as to whether or not you could use plasma concentration to improve the safety of the drug.

THE COURT: Was that modeling then used for the RE-LY study?

MR. CHILDERS: No, sir. That was the modeling based upon the data from the RE-LY study.

THE COURT: Okay. So he took the RE-LY study, and he analyzed the data, and apparently he had different iterations of something you all have referred to as the manuscript.

MR. CHILDERS: Correct.

THE COURT: Then at some point he retired. Dr. Reilly kind of took over that -- I don't remember if it was because of retirement or whatever, but Dr. Reilly then apparently took the last iteration of Dr. Lehr's manuscript and altered it in some fashion more or less, and then that's what ultimately got issued.

MR. CHILDERS: So I don't believe Dr. Lehr retired before Dr. Reilly got involved, but the evidence that we have from Dr. Clemens, who is supervisor to these fellows, was that

Lehr wrote the manuscript, and then -- and he calls him the father of the manuscript.

And you see that also from --

THE COURT: Did he have a more precise explanation for what this manuscript was, what it was done for?

MR. CHILDERS: It was done to -- as the basis for what became the exposure paper that was eventually published in the Journal of the American College of Cardiology.

And so he --

THE COURT: The RE-LY study paper.

MR. CHILDERS: It's an analysis of the data from the RE-LY study, and what they were looking for was how does the plasma concentration affect bleed rate and stroke rate. And so that wasn't done initially in RE-LY. They did a separate analysis to try to figure that out.

THE COURT: Okay.

MR. CHILDERS: So when he did that analysis, at least according to the e-mail from Dr. Clemens, that then Dr. Lehr wrote a manuscript, and he called him the father of the manuscript in that e-mail and said that then the manuscript went to Dr. Reilly, and that Dr. Reilly changed it substantially. And then there was sort of a series, two or three years of back and forth between people in the company before the article was finally published.

THE COURT: And was Lehr out of the picture during

most of that?

MR. CHILDERS: Lehr left in 2012, and the paper was published 2013, 2014.

THE COURT: Well, I'm really puzzled about several things.

MR. CHILDERS: Yes.

THE COURT: One is when I read the MDL order 50 and looked at Judge Herndon's opinion on that, it appeared that relatively immediately before he had issued that opinion, you all in the MDL discovered that there was this Dr. Lehr, and he played this role, and now he can't -- the company couldn't seem to find various things, many of them his personal things, like his own e-mails, his cell phone and then this manuscript.

And so as I understand it, immediately after Judge Herndon entered his sanction order, there was an appeal taken, an interlocutory appeal, which raised only really the requirement that the foreign doctors and personnel come to the United States to be deposed. And, of course, the panel and the circuit found that that was an abuse of discretion and sent it back. There isn't a whole lot of clarity to what, if anything, they intended to do about anything else in that order, but it does seem pretty clear that all they really had before them was the deposition aspect of it. And then not long after that, the MDL settled.

MR. CHILDERS: Correct.

THE COURT: So has anybody ever taken Dr. Lehr's deposition?

MR. CHILDERS: No. Dr. Lehr is a German citizen, does not work for the company. We have asked, in fact Mr. Moskow asked if we could take his deposition, and they said they could not make him come for a deposition.

THE COURT: Is that the only way to do it is to get them to do it?

MR. CHILDERS: There's no vehicle to take -- believe it or not, you can't take a deposition in Germany. And so when we have done employee depositions, they have either taken place in Amsterdam or in London. They have to come outside of the country and be deposed in another place.

THE COURT: Well, what about Dr. Reilly?

MR. CHILDERS: Dr. Reilly has been deposed. He is a U.S. resident.

But I will say this. Dr. Lehr is still a consultant for the company, and through that particular vehicle is how we asked that they make him available for deposition, because we don't have any sort of ability to do that.

THE COURT: Have they refused or --

MR. CHILDERS: They told us they could not make him available.

THE COURT: And you didn't pursue it beyond that?

MR. CHILDERS: No. Other than seeking it through

them, no, Your Honor. We didn't know of another vehicle.

THE COURT: With respect to Dr. Reilly, was he asked about the Lehr manuscript?

MR. CHILDERS: He was. He testifies that Dr. Clemens was just wrong about that, and that he wrote the first draft. That is contrary to what the evidence is from Dr. Clemens. It's contrary to an e-mail from Dr. Lehr that is included in CMO 50 where he says that is the last time that I will let somebody else put their name on a paper that I drafted.

And so what we have is a conflict in the evidence that could potentially be resolved if we had the original information of the manuscript that had been drafted apparently by Dr. Lehr, but we don't have that.

THE COURT: Well, why should I apply Judge Herndon's rulings in this case?

MR. CHILDERS: I'm glad you asked that, Your Honor.

THE COURT: This is not a discovery issue that arose in this case.

MR. CHILDERS: That's where I would disagree.

At the outset of this case, the defendant asked the plaintiff to adopt and utilize all discovery that had occurred in MDL 2385, not to serve any additional discovery, but to rely on that. And then to also coordinate with the Connecticut -- I point to Mr. Moskow because he is the leader of the Connecticut litigation. He's the head of the

plaintiff's executive committee.

And we agreed to do that. We agreed that we wouldn't serve affirmative discovery here, but we would take all of the MDL discovery, and we would coordinate with Connecticut to do additional discovery.

THE COURT: Was there any discussion of Judge Herndon's MDL order and whether that was going to be somehow adopted or used in this case?

MR. CHILDERS: I certainly would say, Your Honor, there was no carve-out. There was no request by the defendant that although we utilize all the discovery, we not utilize any of the sanctions or information that had been ordered by Judge Herndon. So it was our understanding we were taking it as is, and it came to us with CMO 50 as part of it.

This issue has been litigated in Connecticut under the same sort of --

THE COURT: Well, the defendant argued -- and I'll confess that I don't fully understand the relationship between the Connecticut action and the MDL, but they've argued that there is a connection. There was an inter-relationship between those two sets of mass litigation, but that that's not present at all in this case.

And so why should you attribute the conduct of the defendant in the other case to this case?

MR. CHILDERS: I would say because, at their request,

we adopted all of that discovery and conduct so that we wouldn't repeat the discovery here. That was something that -- again, I can't it stress enough, they asked us to do that, and we agreed to it.

We've done the same thing in the Chambers case in front of Judge Land. We didn't send additional requests for what had already been produced.

THE COURT: Has this come up in the Chambers case yet?

MR. CHILDERS: Not yet, Your Honor. Not yet.

And so I would say that why it applies here is because the defendant asked for it to apply here. And what they produced in the MDL is what they produced in the MDL, and it is also what they have produced here because that is what they asked us to agree to at the outset of the case.

THE COURT: To be blunt about it, I wouldn't generally contemplate that agreeing to use the discovery from another case implicitly or explicitly allowed things like discovery disputes to be used in the other case.

Typically, you know, whatever -- I understand in this case there hasn't actually been any discovery disputes raised here.

MR. CHILDERS: Correct.

THE COURT: But typically when that happens, of course the magistrate judge rules on it, and it doesn't become evidence at trial. Obviously whether evidence is produced or

not is a result of discovery, but the steps the parties have to take to file motions to compel or something like that aren't typically admissible.

MR. CHILDERS: And I'm not asking that that be admissible.

What we've asked for is an adverse inference charge to be given to the jury that certain --

THE COURT: Right.

MR. CHILDERS: -- evidence was destroyed or lost along the lines of what had been ordered in the Connecticut cases.

And in this particular case, even if you were to throw away the discovery dispute that happened in MDL 2385, Dr. Lehr's documents still weren't preserved properly at a time when the company was on notice that they needed to preserve them.

The findings are the same. We can't go back in time and undo the fact that they destroyed his laptop, his cell phone, his personal computer. We're still stuck with the fact that they destroyed that evidence, and we have the same burden proving the same issues now that were going to be proved in the MDL.

THE COURT: Obviously I'm troubled by all of this. I know that the MDL has settled, so Judge Herndon's order 50 wasn't really reviewed by an appeals court.

MR. CHILDERS: Sure.

THE COURT: And then secondly, he didn't even decide at the time that an adverse inference instruction or loss of a claim or denial of defense or something like that was an appropriate relief. He kind of put all that off, and it troubles me now to be a judge who is not at all involved with the proceedings that were before him that resulted in his order to then sort of pick that up wholesale and say it's binding here because you agreed that we're going to use discovery from an MDL case when there's no explicit discussion between the parties about what's the effect of order 50 and the unavailability of Dr. Lehr.

MR. CHILDERS: Well, if I could point out to Your Honor sort of the things that are missing, why these documents would have been important to this particular case.

Obviously you have heard a lot about therapeutic range and plasma concentrations. That's the information that -- that was Dr. Lehr's wheelhouse. Those were the issues that he worked on. Those were the issues that he apparently provided for that initial manuscript of the Reilly Lehr paper that we to this day don't have. We will never have that paper.

THE COURT: Well, but what you do have is what Dr. Reilly did, which is really the final product.

MR. CHILDERS: Right.

THE COURT: And I understand that Dr. Lehr was perhaps the originating author. And I recognize, you know, that you

probably hoped that you could get ahold of one of his so-called manuscripts and find something that greatly and directly contradicts Dr. Reilly's ultimate conclusions and the position that the defense takes here.

But the fact is, you've got the report that was issued, which was what he played the role in, and you've got the final product, and I guess I don't know why that isn't enough given the posture of this case here now.

MR. CHILDERS: Well, I can tell you, if we look to case law here in this same court, from Judge Eifert in the Ethicon case, she looked at what duties does a company -- in that case, it was Ethicon -- have as far as maintaining custodian files. And she made it clear that key players have to be identified, and their files have to be maintained and preserved.

There's no question here, for one, Dr. Lehr was a key player. He analyzed the very issue that this case is centered on, which is plasma concentration of Pradaxa and how that affects safety and efficacy. And there's no question the defendants did not maintain his custodial file at a time when they were on notice of litigation and should have.

So, for one, the case law here in this same court tells us that is an appropriate --

THE COURT: Okay.

MR. CHILDERS: -- that an adverse inference may be an

appropriate remedy for that particular situation.

If you look to some of the findings in CMO 50 -- and I understand Your Honor is hesitant to adopt them wholesale, but this was very extensively litigated before Judge Herndon, who had all of the facts in front of him.

And if you look at certain things such as on page 25 of his order, CMO 50, Judge Herndon noted that the MDL court is stunned that Lehr was not identified by Boehringer as a custodian with potential knowledge about Pradaxa. This is after he's detailed in great detail the roles that Dr. Lehr played.

And then on page 26, Judge Herndon went on to say that there is no question that Dr. Lehr's documents should have been the object of a litigation hold. Again, the same issue here. It's the same litigation. We're using the same documents. We're using all the same evidence.

In fact, the only reason we're not in front of Judge Herndon is because he just stopped taking cases. The MDL shut down, and that's why this case is here. I'm kind of surprised it didn't make it to the MDL frankly before the MDL shut down based on when it was filed, but it just didn't.

Then in that same order -- and this is important, Your Honor -- on page 27, Judge Herndon noted, similar to what I think Judge Eifert found in the Ethicon case, Boehringer does not get to pick and choose which evidence they want to produce

from which sources. They have to produce to us evidence that is responsive and related to our claims. And when they don't, it says plaintiffs are entitled -- I'm sorry.

He also pointed out that the issues that are not known that we don't know because we don't have those documents on page 28, were what annotations were contained in the personal versions of Dr. Lehr's documents relating to the exposure response paper, what statements he made to other people in the company. They went back and forth extensively on this in his share room, which is a particular -- sort of a cloud kind of thing that is used by the company to communicate back and forth.

THE COURT: I assume that to the extent that he communicated by e-mail or something like that, there was somebody else in the company who was identified, and there was a litigation hold on them.

Have you seen things that Dr. Lehr exchanged with them?

MR. CHILDERS: Some. But what we don't have is what he would have done in the share room, what he would have annotate -- there are a lot of documents that have -- like, if you track changes on a Word document, you can see, if you are passing them around with multiple people, their initials. It has the time they put it in, the entry. It says what they have to say. We don't have that with Dr. Lehr's initial draft

because we don't have the draft at all in particular.

THE COURT: So are you really then just focused on the so-called manuscript and the failure of the defendant to preserve and disclose it?

MR. CHILDERS: That's the only thing that we know that existed that we don't have. What we don't know is what we don't know, Your Honor.

But we know from at least Dr. Clemens' e-mail, and then Dr. Lehr's own e-mail, there was a draft that he produced that we don't have.

THE COURT: I think you pointed out that in one of the Connecticut orders, in one of those two cases, that the judge agreed to allow an adverse inference instruction but fairly narrowly and wasn't going to allow evidence?

Do you know what I'm talking about?

MR. CHILDERS: I do, Your Honor.

So it was plaintiff's position that a jury instruction can be properly argued to the jury during closing argument. The judge in Connecticut did not agree with that, and so plaintiffs were not allowed to sort of set it up for the jury in closing argument as to why it was important who it related to. But then she read the instruction to the jury at the end.

While we were pleased that the instruction was read, we felt it was somewhat hollow in that --

THE COURT: I don't have it in front of me, but did it

refer explicitly to Dr. Lehr?

MR. CHILDERS: It did. And it said that the company just -- that the -- whatever they did to his files was not inadvertent, meaning they did it on purpose.

It didn't -- and then in the second trial, I believe they even said destroyed. Judge Morgan told the jury they had destroyed it not inadvertently and then allowed the jury -- explained -- and that it had the sort of adverse inference and said that the jury could or could not --

THE COURT: Right.

MR. CHILDERS: -- choose to take that as being adverse evidence to the party who destroyed it.

So what we have here is -- and I understand Your Honor's issue with use of what happened in the MDL here. I don't see this as any different.

If this case had gone to the MDL, and it didn't settle, it would come right back here to you for trial because it would have to be sent back to the transferor court. It wouldn't have been tried there unless Lexecon had been waived, and I can tell you that wouldn't have happened, and we'd be in the same boat.

The only difference we have here is we have utilized all of the same stuff. We just didn't go to the MDL to begin with and then come back to you. And so I do believe that what happened in the MDL in its entirety applies here.

THE COURT: Okay. I don't want to run out of time.

MR. CHILDERS: Yes, sir.

THE COURT: All right. Tell me about the other doctor. Is it Dr. Brueckmann?

MR. CHILDERS: Dr. Brueckmann, also a key player, no question about that. She is in charge of the pediatric clinical trials and has been for a number of years. Prior to that, she worked on Pradaxa. She's been a player in Pradaxa since before it was approved for sale.

In her particular case, there was about a two-year gap in which her e-mails weren't preserved. And what the defendants have said is, well, we tried to go capture any internal e-mails that she sent to folks, and we gave you those --

THE COURT: As I understand it, their explanation is that they changed their software or something by which they do their litigation hold.

MR. CHILDERS: I understand. But there were only three people that that seemingly affected, and there are a whole lot more people that they gave us documents for. I can't -- I don't know the explanation for that. I don't know why it would only affect those few.

But Dr. Brueckmann is one of the most key people because, in fact, she is the one who is in charge of sort of putting together what is called the Diversity clinical trial,

which is where Mr. Moskow was explaining to Your Honor they're actually utilizing, the company is actually utilizing plasma monitoring to dose Pradaxa in children based on the information they got from the adult clinical trials, including RE-LY, as to what is the most safe and effective level of Pradaxa for a patient.

She still works for BI. It's not as if she left the company, and we forgot about her. Or there was some gap in litigation and, therefore, we stopped the litigation hold and then picked it back up. There's never been a stop in litigation. There's been a Pradaxa case pending since 2010, '11, '12, somewhere in there, I'm not sure. But there's never been a time where there just was no litigation happening.

And so while I understand their argument is, well, we just had a glitch in our software, it didn't affect some of these other folks who didn't in particular have the duties that Dr. Brueckmann has. And as you'll see in the trial, that Diversity clinical trial and the fact of utilizing that particular dosing algorithm would be central to our case, and what we don't have is any communication she had with anyone outside the company.

And, again, you gotta consider this is a clinical trial, meaning they've got people out in the field who are running this clinical trial. And she testified when Mr. Moskow asked her -- we did ask her about this at her

deposition -- yeah, I do communicate with people outside the company, and I don't know how many times I've done that.

And I wouldn't have had e-mails saved into --

THE COURT: What do you make of the defendant's argument that they were able to go to other sources and obtain copies of much of this requested information and thereby significantly narrowing the window of time for which they can't produce her e-mails?

MR. CHILDERS: I don't think they can -- I don't think they can narrow the window of time. They can only capture what Dr. Brueckmann sent internally in the company. I don't think they argued to Your Honor or to the Court that they were able to go out and capture e-mails that she sent to third parties.

THE COURT: Right.

MR. CHILDERS: And so what we've seen in several of the other documents that have been produced from other witnesses, the communications going back and forth with some of these third parties you're going to see again are key here. People are asking for information outside the company, and then it's not getting to them. The stuff that is known inside the company is either not told to them or they're told something different, and that's the kind of information we don't have.

If Dr. Brueckmann was asked a particular question by

someone outside the company about, in particular, use of this algorithm to dose these children, we don't know what she told them back. She may have said we should be doing this with all of our patients. She may have said we've considered doing this, but until this litigation is over, we better stay away from it. Who knows.

But we do know we don't have those e-mails, and she's the person who is in charge of that particular aspect of the clinical trial.

THE COURT: The way the new rule reads with regard to ESI, it suggests to me that trial courts are to consider an adverse inference instruction as one of the more severe, perhaps the most severe sanctions, right up there with precluding a defense or granting summary judgment or default judgment on a claim. And that to get to that point, I'd have to determine that the defendant acted with intent to deprive.

MR. CHILDERS: Your Honor, if this was -- if there wasn't CMO 50, if there wasn't a long history of this happening, I don't think I'd be standing here right now. But what we have is this is yet again another example of the defendant knowing that a litigation hold should have been placed and should have been maintained with this -- with regard to this particular person, a key player with Pradaxa.

If it was one month, maybe that's okay.

THE COURT: Has anyone --

MR. CHILDERS: It was two years, Your Honor.

THE COURT: Has any other court looked at --

MR. CHILDERS: The Connecticut courts did, Your Honor, and they chose not to include this in the adverse inference charge. They stuck just with the Dr. Lehr issue.

THE COURT: So how could I, then? I mean, I'm not even hearing the evidence of the defendant's conduct. So how could I make a ruling under Rule 37 that the defendant acted with intent to deprive the plaintiffs of the use of the information?

MR. CHILDERS: I think, Your Honor --

THE COURT: It's just a prerequisite as I read it to --

MR. CHILDERS: I think, Your Honor, if you were to look at it in conjunction with what occurred prior to that particular litigation hold fail, and look at the extent of time, clearly nobody took any steps in two years to realize, oh, wait, we're not keeping her e-mails. Again, it's not a situation where whoever is in charge of the litigation hold at one of these -- at the company or one of their law firms missed it one month. It was two years. And during that two-year time is when the Diversity trial was being prepared to be rolled out. It's still ongoing right now.

And so --

THE COURT: In these other actions, like in the

Connecticut case, have you tried to chase down any of these people with whom Dr. Brueckmann would have corresponded to see --

MR. CHILDERS: We don't have any of the e-mails that she sent outside of the company. That's why we can't --

THE COURT: But I'm asking if you've been able to identify by questioning her in deposition or through other discovery means who it is that she would have communicated with.

MR. CHILDERS: We did ask her, and I think she identified some of the companies who they were working with on diagnostic tools, like handheld devices to be used to monitor blood levels. But I don't -- I don't recall beyond that, Your Honor.

THE COURT: Okay.

MR. CHILDERS: I think the only other issue I wanted to address is timeliness. They raise the issue it's not timely, and they relied on Judge Goodwin's order in the Travelers versus Mountaineer Gas case. In that order, Judge Goodwin specifically found there's no particular time under Rule 37 when you have to file a motion for spoilation.

The issue in that case -- and he seemed to believe that asking for a case to be dismissed was much more significant than an adverse inference charge because he said they're seeking the ultimate sanction.

THE COURT: Sure, I would agree with that.

MR. CHILDERS: And because of that, I want to look at this timeliness, why this is just coming up now. And what he noted was the parties weren't even -- the plaintiff had no idea that this was going to be raised, that this was even an issue in the case.

That's not what happened here. Spoilation has been at issue in this case since the MDL was still in play and has been litigated twice in Connecticut, so it's all the same stuff. It's not a surprise. It's not something that was not on their radar. And in looking at Judge Goodwin's order, which is the only case the defendant relies on, I don't think that would apply at all in this situation, Your Honor.

THE COURT: Okay. Thank you.

MR. CHILDERS: Thank you, Your Honor.

MR. IMBROSCIO: If I may, Your Honor. I had put together a presentation. I'm going to skip through it pretty quickly and try to respond to some of the Court's questions.

THE COURT: Okay.

MR. IMBROSCIO: But before I get into it, let me just try to correct some of the facts because I think the Court has a misimpression on some of the facts that I just want to lay out.

THE COURT: Okay.

MR. IMBROSCIO: First, the RE-LY study was begun back

in '04, '05, and Dr. Reilly was the head of the RE-LY study. And one of the things they decided at the outset to decide -- to look into is this issue of plasma levels. And so part of the protocol was to take these plasma levels and see what can be made of them.

Notably none of the other -- well, certainly not Eliquis or Xarelto did any of this, so BI did this sort of testing.

So they get the data, and one of the preordained, ah, analyses that was going to happen was let's see what the exposure response relationships were, what ultimately became the exposure response paper. Dr. Reilly was the original author of that. He did the first draft. And I'll run through -- you'll see it, but there's no dispute that he was the primary author and wrote the first draft.

Two, there is -- well, let me actually run through because I have to get the data on it. And Your Honor has a copy of this, but I run through the legal aspects. Your Honor has a firm grasp of the need to establish intent to deceive, which I don't think they even make an effort to do that. But this is just some background facts on some of the questions Your Honor was asking on slide 7.

BI has preserved and produced documents from more than 150 different custodians and 45 different central sources, shared drives, other things of that sort, ultimately resulting

in, you know, almost 50 million pages of documents and produced I think now upwards of I want to say 60 depositions. So that's point number one.

As it relates to -- well, actually I should mention this.

So the manual mentions the importance of sharing discovery. And as Your Honor mentioned, of course, you know, it makes good sense to share discovery that has occurred. The notion that we would have shared this discovery taking on an order that we vehemently to our core disagreed with, that doesn't make any sense. We would never have done that, and that was never the implicit or explicit aspect of sharing the discovery. It was the right thing to do to share this data. And they have also taken a whole bunch of additional discovery since the conclusion of the MDL.

Here's something -- I mean, to be clear, Dr. Lehr's e-mails, there's no dispute, they exist. They were preserved. Let me say that again. His e-mails were preserved, there is no dispute. They were not recycled, and so there's no dispute that they have all of these e-mails. I think it's roughly 4,000 e-mails.

And there's no dispute that all of the documents that were on the central server, that were on the company documents were preserved. Put it all together, it's about 20,000 documents and families that they have from Dr. Lehr.

THE COURT: And none of these included Dr. Lehr's so-called manuscript?

MR. IMBROSCIO: There's a reason for that. There was no Dr. Lehr manuscript.

To accept -- there is a string e-mail that they have cited to now from Dr. Clemens that says Thorsten was the father of the manuscript, Paul took it over and changed it significantly. That's just wrong. The sworn testimony from Dr. Reilly is that he wrote the first draft. He shared the first draft with the co-authors.

Because we had --

THE COURT: Was Lehr a co-author?

MR. IMBROSCIO: Yes, he was, absolutely.

And the second piece of evidence they relied on today is an e-mail from Dr. Lehr saying -- and I wrote this down because it's just wrong -- saying never again am I going to have someone take over a draft -- a paper, quote, that I drafted. That's just wrong. The e-mail actually says where I did the primary analysis.

There is no dispute that Dr. Lehr was the computer guy doing all of the computer models and all the output and all the simulation. The record -- there are probably hundreds, maybe thousands of versions of those simulations that have been in the discovery record. There is no dispute that the plaintiffs have all of that.

And to accept the plaintiff's missing first draft theory, you've got to assume that Dr. Lehr wrote this draft but did not store it on the central drive, did not e-mail it to anyone, because all of his e-mails were preserved. That's just fanciful.

I think what happened is Dr. Clemens just got that issue wrong. And it's important, it's relevant that they only have the single e-mail that suggested that there was some first draft. There is no mystery first draft, and the record I think is very clear on that.

This is what happened, and there's no dispute with what happened, Your Honor. When Dr. Lehr -- he didn't retire. He is a young guy. He is probably in his early thirties. He just went to a university professorship.

When he did that in the late summer of 2012, he was not on hold. That was a mistake, no doubt about that. We know in retrospect, no, that was a mistake. What happened was his laptop and desktop and his blackberry were recycled in the normal course. That happened. That was a mistake, it shouldn't have happened. It doesn't change the fact that all of his e-mails were preserved and that all of the material on the company server was preserved.

The reason why that is important is in his own affidavit, which was obtained in connection with the Judge Herndon proceeding, which Judge Herndon cites, he made very

clear that he stored his documents on the central server. He would put things on his laptop when he was traveling, but he would be good about uploading things back up to the central server which, again, the plaintiffs have.

He also said -- that's paragraph 6 of the Lehr affidavit.

He also said it was not his practice to make notes on these materials. He can't rule it out. But the notion that there was some cache of documents that were missing, there's no evidence of that. That's just not the case.

And certainly, back to the legal standard under Rule 37, there's no suggestion of an intent to deprive, which is essential here. If there were an intent to deprive, his e-mails would not have been preserved. You know, something would have happened to wipe out things on the central server. What happened here was a mistake, the kind of mistake that the new Rule 37 says cannot, under any circumstances, lead to the kind of adverse inference that the plaintiffs want here.

We have in the record an affidavit from Jonathan Redgrave, who is a world recognized expert. And he essentially offers the opinion, to the extent Your Honor wants to look at it, that there was nothing here suggesting in his expert view any intent to deprive when it comes to Dr. Lehr. And he points out the fact, you know, really that the committee notes especially, you know, talk about needing to

take reasonable steps and not perfection.

Obviously preserving Dr. Lehr's documents, his laptop, not recycling his laptop and desktop would have been closer to perfection. But the company still took far beyond what we believe to be, ah, reasonable steps. Again, I mentioned at the outset, we think the plaintiffs have not really even embraced the correct legal standard, and they essentially just rely on Judge Herndon's ruling.

Let me just run through now -- let me go to slide 24. As Your Honor said, Judge Herndon himself did not make the ultimate decision here about whether there was any prejudice. He reserved that and ultimately never ruled on that. So this notion that there would somehow be -- I think what they are arguing essentially as collateral estoppel we think has no -- not just no practical place here, but certainly no legal place either.

In Connecticut, the judge there -- first Judge Moll, and then Judge Morgan adopted her initial rulings -- basically said I think it's one and the same proceeding because the Connecticut proceeding was open alongside of the MDL proceeding and ultimately sort of struck a balance.

The court said I get it that this could be very, very prejudicial. I'm not going to let evidence of it in. But the court sort of felt bound sort of through some notion of law of the case or collateral estoppel that needed to adopt -- needed

to accept Judge Herndon's ultimate conclusion.

Again, we disagree with that, and we will be addressing that issue, you know, at the appropriate time with an appellate court. But it's very different from the situation here because implicit in that ruling was the notion it was all one big case and, therefore, that ruling in that case was the same as the ruling in this case.

We disagree with that, but I think what is instructive is the court's acknowledgement, in granting our motion in limine on keeping out evidence and argument about it, that this stuff is really really prejudicial. That's why the rules, you know, put adverse inference up there with default judgment and some of the other more extreme circumstances, which we don't think the record here provides.

This is the father of the manuscript e-mail, slide 29, from Dr. Clemens, but let me just show you what else is in the record.

Dr. Reilly's distribution of what became the Reilly paper, the exposure response paper, in January of 2011 he circulates the first draft of that paper. So Your Honor was under the impression that Dr. Lehr did a first draft, and then Reilly took it over. That's actually not the case. The record is undisputed that Dr. Reilly wrote the first draft.

This is him circulating that first draft. This is him circulating six months later the second draft to the

individuals, the outside doctors who were involved in that particular paper.

Moreover, Dr. Reilly testified unambiguously that he was the first named author, he wrote the first draft. He said that in his deposition of January of '17, and he also testified to that in the -- I think that's the Boone trial.

Here is the -- just to take a step back for a second, Your Honor. The implicit argument they have here is that there was some secret about a draft therapeutic range, and that it somehow got excised before any documents came into possession. That is just factually wrong. They have all of the drafts, dozens of drafts of this article with the range in it and when the range was taken out with a very clear documentary record of why it was taken out.

So this notion that there is something missing substantively, there's just no support for that either, Your Honor. That is all in the record. That is a big part of the evidence they put on at trial. And so this notion that there is something that they are deprived of that they're missing, there is no factual basis for that in our view.

And this is an early draft of the exposure paper back from December of 2011 with the range in it. The range then came out. That record is all very clear, and they have all of that.

It might be a different story if there were

suggestions that there were an early draft with a range in it that there is no existence of. That's not the case. They've got the earlier drafts. I think one of the earlier drafts said 30 to 300. Ultimately it was I think 40 to 215. I think Mr. Moskow earlier referenced they ultimately settled on 40 to 215. That's because there were lots of theoretical drafts. That's the way the article developed, and ultimately the company picking evolved past that.

There was a reference to management sort of making this decision. The management they're referring to was a doctor by the name of Jeff Friedman, who was essentially the head physician in charge of cardiovascular safety. His view was, from a medical point of view, it's not appropriate to list a therapeutic range because the relationships between bleeding and stroke and plasma concentrations are far too complex, and you could end up doing harm. That's -- that's very clear in the record as well.

This is one of the e-mails. And what's important here in this e-mail on slide 37 is Dr. Lehr himself writing to Paul Reilly, around the time of this discussion when it comes out, Dr. Lehr himself says, yeah, I don't think we really need the range. It really doesn't -- it's not really an important part of the article. In his words, the manuscript doesn't lose anything if you were to take out this range.

So this notion that Thorsten Lehr was fighting, you

know, to his death to keep a therapeutic range in the draft, that's just -- that's a figment of the plaintiff's imagination. That's their spin on this. Factually it's not true.

Let me skip quickly to the Dr. Brueckmann issue. I think that's a really simple one, as Your Honor said.

As Mr. Childers said, the Connecticut court looked at this issue and concluded there is no -- not intent to deprive, that's the federal standard, but no suggestion anything happened here other than an error. And the efforts that were taken to remedy it more than adequately addressed these issues. Again, we don't think there's any intent to deprive. There's no evidence that really anything is missing.

Dr. Brueckmann communicated with people in the outside world, but I think she was clear that in those communications, it was often the case -- you look at the e-mails in this record, and it is the rare case where there is one person communicating with one other person. The average number of people in these e-mails is probably 15.

And so what would happen is you would need an e-mail only from Dr. Brueckmann to some outside person or to one of the two other custodians during a very limited range. And can we rule that out? No, we can't. But the larger record demonstrates that there is a tremendous amount of information available from Dr. Brueckmann specifically, and we have the

stats on slide 39. Really it's a remarkable number of materials that have been produced from her. So the suggestion that anything substantive is missing we think is not appropriate.

I'm happy to answer any questions.

THE COURT: All right. Thank you.

Mr. Childers, you want to briefly reply?

MR. CHILDERS: If I could, just in regards to some of these slides, Your Honor.

I don't know if he gave you a copy of it or if it was just on the screen, but --

THE COURT: Yes I have it.

MR. CHILDERS: Slide 9, one of the things it notes, it says MDL rulings do not justify relief plaintiffs seek. The MDL court found bad faith. That's as strong a finding as you can -- a court could make in this situation. So to say that doesn't justify the relief we seek I think is just -- is just inaccurate.

In regard to -- and I'll just skip around to a few of these, Your Honor. I was trying to make notes.

Dr. Lehr's declaration I think that was put on the screen, Judge Herndon considered that. In fact, in CMO 50, he said I have gotten this declaration from Dr. Lehr, and I understand we have all his e-mails. That just even more shows me that they should have held the rest of his files. They

kept his e-mails, but destroyed everything else. And so he made a specific note of that after referring to the Lehr affidavit, Your Honor.

On slide 16, I think it's titled No Intent to Deprive, that's not what Judge Herndon found. In CMO 50 on page 37, he specifically found that -- he called them maneuvers by Boehringer in discovery were by design, that they did them on purpose, and that was one of the reasons why he then went in to find they were done in bad faith.

And we quoted in particular in our motion the very specific findings about this was in bad faith, this was in bad faith. It was on, I believe, pages 44 to 45 of CMO 50 where Judge Herndon very specifically went through what was in bad faith, which clearly would fit into the intent to deprive.

I thought it was a bit ironic after arguing that plaintiff's experts should not be able to opine on intent, they give you an affidavit from a litigation -- a discovery expert telling you about their intent and what they were supposedly doing when they destroyed these documents. I don't know how on one hand they can say our experts can't do that, but you should rely on this gentleman from Redgrave LLP to tell you -- for him to come in and tell you what the company's intent was. I don't think it's proper for that, so I certainly don't think Your Honor should be considering that.

Our arguments are not a hundred percent relying on the

MDL court's finding. We are also looking at what the Connecticut courts found. In two different situations -- or excuse me. In two different cases involving the same issues, both of those courts have also found that the burden had been met, that the evidence was intentionally destroyed, and that an adverse inference charge was appropriate.

In this case, we have presented Your Honor with the nexus between what is missing and what plaintiff would be -- would have presented and will not be able to present to the jury as a result.

The fact -- I think it was around -- on page 29, there is the e-mail from Dr. Clemens that I had mentioned to Your Honor where he calls Dr. Lehr the father of the manuscript. Right after showing you that, Mr. Imbroscio said it's undisputed that he wasn't the drafter of the manuscript. This e-mail in and of itself creates a dispute.

I didn't draft this e-mail. None of us drafted this e-mail. This was drafted by an employee of Boehringer Ingelheim who said Thorsten Lehr was the father of the manuscript, and then Dr. Reilly changed it. Whether or not Dr. Reilly disputes that is a dispute at its very essence.

THE COURT: What about all of the other versions of this that defense counsel noted that have been produced and the e-mail discussions and otherwise where they talk about therapeutic range, what it could be, whether it's in or out?

MR. CHILDERS: We've seen quite a bit of those. One thing that we see every time we actually have a draft of the papers are those internal changes, notes, cross-throughs that are made that we don't have from the initial paper that, at least according to Dr. Clemens, was drafted by Dr. Lehr. We don't see any of those comments because we don't see the paper itself.

And those are comments that are not reflected in the e-mails. They're just in the body of the actual document when the person who is reviewing it makes their comments directly on the document itself. And so while we do have some e-mails relating to Dr. Reilly's draft, we don't have any that relate to Dr. Lehr's drafts, and we don't have the actual draft itself.

Sorry, Your Honor, if I could just make sure I haven't left anything out.

In the Boone -- in the Boone and Gallam cases in regard to Dr. Brueckmann and whether or not the litigation hold in relation to her e-mails should be something that was subject to an adverse inference charge, the court didn't actually hold an evidentiary hearing on that issue that I recall, and I don't know what in particular was relied on other than the actual papers. But I guess what I would stress to Your Honor again is just switching software and having a glitch does not comport with losing two years -- spending two

years not collecting this particular key player's e-mails.

That doesn't make sense. It doesn't take two years to switch your litigation hold software. It takes days at most. So why is there two years worth missing? I can't tell you, but I know that's not just a glitch. There's no way that's just a glitch.

THE COURT: The problem I've got with all this is how do I make a finding consistent with Rule 37 when none of this is before me?

MR. CHILDERS: Well, I understand, Your Honor. And it's an awkward position I guess because we had agreed to do all these things so we wouldn't duplicate efforts. And it's always been plaintiff's belief that that meant that whatever happened in one court would be considered what happened in all of those courts. And if we made that mistake, that's our mistake.

Finally, the last slide was slide 41 where the judge in the Gallam and Boone cases -- judges, excuse me, there were two different judges -- where they didn't allow the evidence to be argued to the jury. That's under a whole different system of evidence. That's the Connecticut Rules of Evidence. That's not the Federal Rules of Evidence. So to the extent that Your Honor is inclined to give an adverse inference charge, plaintiffs would and do believe that any charge to the jury is something that should be properly able to be argued in

a closing argument, Your Honor.

THE COURT: All right.

MR. CHILDERS: Thank you, Your Honor.

THE COURT: Well, thank you for your arguments. Before we adjourn, there are a few matters that I want to take up in anticipation of the proceedings.

So we reset the trial to October 1st. I've set aside 14 business days. I guess there's a holiday in there. I've set a pretrial conference for September 17th. But I note that there are a number of other things that you all indicated you were going to discuss, or maybe I gave you some direction to in my order on pretrial activity, so I thought I would bring those up.

So, first, have the parties decided when and how you're going to exchange deposition designations? You've each cited a whole lot of people who were going to testify by deposition. Have you had any discussion about when you will exchange your designations?

MR. CHILDERS: We haven't, Your Honor.

And I can tell you we're actively having that conversation about the Chambers case, and we can --

THE COURT: Okay.

MR. CHILDERS: I don't know if the same person from their side is going to be handling that, but it's an ongoing discussion that I think can be had in both cases.

THE COURT: What's your deadline in the Chambers case for that; do you know?

MR. CHILDERS: July 5th, I believe, is when we are submitting. Obviously --

THE COURT: When is the trial scheduled to start?

MR. CHILDERS: August 13th, Your Honor.

THE COURT: August 13th. Okay. So you expect then to exchange designations in early July for that case.

MR. CHILDERS: Yes, Your Honor.

MR. IMBROSCIO: One thing I would say, Your Honor, is we have now gone through this exercise twice in Connecticut. I think the circle starts to get smaller and smaller, and it's an easier exercise, but we do need to go through it.

THE COURT: Okay.

MR. CHILDERS: I agree, Your Honor.

THE COURT: Well, I won't yet impose a deadline, but what I would expect is that either before -- hopefully before you start the Chambers trial, because I know you'll be really busy once that goes, that you can advise the Court as to your agreement. Whether it's the same designations or something different obviously you all have to address. But I would hope and expect that before you get into the Chambers trial, you'll be able to communicate to this court that you have a definite deadline and plan, if not already an agreement, on what you're designating.

MR. IMBROSCIO: If I may on that, Your Honor.

THE COURT: Yes.

MR. IMBROSCIO: As a very -- having been the chief person responsible for this from the defense side in the last two trials, one of the challenges is, I think given the number of witnesses that were deposed, there starts out being a pretty wide range of potential people, and then as the trial progresses it's a smaller number. What we look for is to try to get to that smaller number earlier, and that seems consistent with what you're saying as well.

THE COURT: Okay. Good.

I will want to set a new deadline -- I don't know if we may have put this in some sort of standard language in the scheduling order, but I wanted to discuss when you would expect to submit proposed instructions and proposed voir dire. You know, our typical order just has people do that as part of the pretrial order. I don't know whether you have those things -- at least the voir dire is usually included in the integrated pretrial order.

Was that the case here? Did you all do that already or do you know?

MR. IMBROSCIO: I know we were on the precipice of exchanging them or submitting them, and it just didn't -- because of the trial delay --

THE COURT: And I know a couple days ago, I guess, Max

talked with one of you about instructions because I guess we had sort of left standing the deadline for instructions. And I sure didn't want them filed at that point, we had just ruled on summary judgment, and we had all of those other things.

So do you want to discuss and then reach an agreement to provide instructions, proposed instructions and proposed voir dire to me? And I'll just leave it to you to get back with us soon and tell us what deadline you've agreed upon?

MR. CHILDERS: That's fine with us, Your Honor.

MR. IMBROSCIO: Yes, Your Honor.

THE COURT: That's the way I would prefer to do it.

And then, likewise, I would expect you to reach agreement on how you're handling trial exhibits. I know you, I guess, talked about putting each other on notice about witnesses and maybe even on notice about when you expect to introduce exhibits.

MR. IMBROSCIO: Uh-huh.

THE COURT: When do you intend to have -- are you all doing notebooks for most of these trials, jury notebooks or not?

MR. IMBROSCIO: We did not do jury notebooks. We do have an arrangement in place that seemed to work well, at least from our perspective, on notice on the exhibits that were going to be used with a witness. We would be fine with that proposal.

THE COURT: Well, let me do this. What I think I'll do is direct that the parties communicate about all these things and see if you can reach agreement or stipulation as to the matters we just discussed and report back to the Court sometime -- I'll give you a deadline sometime in that first week of August, sometimes toward the end of whatever that first week is. And that will be your reminder and my reminder that you're to have these discussions and resolve these things, and then you can tell me before you get bogged down in the Chambers case if there is some expectation or you believe that there is some change in circumstances that's going to make it more difficult to be able to give me these things.

I really want and expect to have these things before the pretrial conference on September 17th because I want to be able to address any problems at that point. I don't expect you to be prepared to fully argue instructions, of course, but at least -- you know, you have tried these cases before, and by that point you should have a pretty good idea of what each is going to offer and what is appropriate or not appropriate. So I would hope we could have a pretty good discussion at the pretrial conference on what each side believes will be entailed in coming up with final instructions.

I also intend to do some type of a very limited jury questionnaire, and I expect to do that probably by the first part of September. And I'm really going to just ask

essentially two things. One, I expect to ask jurors to advise the Court if they have some sort of unusual circumstance that would justify excusing them from the jury pool for the period in October and putting them on notice that this jury pool will be used to pick a jury to try a case that is expected to last through two or three full weeks.

As I told you before, in this district that's very unusual, so it's difficult for people to set aside that much time. And I don't want to find out, you know, the day we start a trial that we've got a bunch of jurors in here that have very legitimate requirements such that it would be very difficult for them to serve. So I'll ask them to identify anything like that well before we -- hopefully before we have the pretrial.

Then also I would expect, with your all's input, to ask some very general, nonspecific questions about the extent to which jurors or their immediate family are or have been on blood thinners or something like that. I don't want to name the product. I don't want to invite jurors to start looking for the news. But I do think it would be important to find out if people are on blood thinners of any kind or have some significant medical history involving them or have the condition of AFib where you certainly want to explore the extent to which they may have discussed some type of blood thinner treatment or something.

So keep that in mind. As I said, I would expect to get a questionnaire of some type out in very early September, probably right after Labor Day, and expect jurors to respond pretty quickly and be prepared to talk about it further at or before the pretrial conference. So that's my general plan.

MR. CHILDERS: Your Honor?

THE COURT: Yes.

MR. CHILDERS: In the Connecticut trials, we had an agreed upon -- jury selection was a little different there, but we had an agreed upon set of eight or ten questions, ten questions. They were more specific. But would it be okay if we got together to try to see if we could -- it helped us greatly to limit the jury pool.

THE COURT: Absolutely. Sure.

MR. CHILDERS: Is that all right with you?

MR. IMBROSCIO: Yeah.

MR. CHILDERS: Just to see if there is anything that may be appropriate for --

THE COURT: All right. So I will include then, when we do this order, requiring you to get back with the Court early in August, that you include the prospect of an agreed jury questionnaire of some type --

MR. CHILDERS: Yes, Your Honor.

THE COURT: -- and see where you folks get with that. So I'm not going to try to lay all this stuff out in

the order. I'm going to probably just say that by a certain date in the first part of August, the parties are to report back about the matters discussed today and tell the Court the extent to which you agree or you have disagreements that need to be resolved by the Court, and then you can tell me in some fashion your plan.

If you work these things out, we can either do this by phone or even I would expect you to file some type of report maybe in advance of some sort of a status conference the next week and see where we stand. But we'll try to do all that before you actually get started in the Chambers case.

(Off-the-record discussion with Law Clerk.)

THE COURT: Max reminded me that I wanted to clarify something else just to make sure I don't make a mistake when I resolve this spoilation question.

Do you folks agree or disagree as to whether or not Dr. Lehr's so-called manuscript and notes -- are those ESI? Are those electronically stored information or are they something else?

MR. IMBROSCIO: I think everything that is suggested to be missing is ESI with the exception of there is reference in his affidavit about having some binders in his office. Those were hard copy. But everything else was ESI.

THE COURT: What did he say about the binders, that he no longer has those?

MR. IMBROSCIO: He says he no longer has those, yes. But I think he says that they were copies of things that were electronically stored. I think that's straight out of his affidavit, Your Honor.

THE COURT: What do you all say?

MR. CHILDERS: I assume that -- I don't assume anything, Your Honor.

They may have had handwritten notes, we don't know. But I think most of what is at issue would be ESI.

THE COURT: All right. Then is there anything else the parties -- so you've got the Chambers case, and then was there another one scheduled after that before --

MR. MOSKOW: There's a case scheduled in Connecticut, Your Honor, Bedsole, which is scheduled for September 12th. Jury selection is starting -- jury selection is likely to take two to three weeks under the Connecticut rules.

MR. CHILDERS: It's crazy.

THE COURT: All right.

MR. LEWIS: We had just two housekeeping matters, Your Honor, if I may.

THE COURT: Sure.

MR. LEWIS: Number one relates to the Court's factual findings in the motion for summary judgment. There was some concern on our side that the way they're phrased in the Court's order could be used by perhaps other folks in other

litigation to say that the Court made findings of fact as articulated in that motion for summary judgment. I don't particularly read it that way. I read it as the Court saying these are disputed issues of fact, but I just wanted to make sure.

Is my reading on that correct, that these are disputed issues of fact?

THE COURT: Yes. I wouldn't purport to be finding and concluding facts. What I tried to do was to recite the evidence. And when I stated something as a fact, I thought it was pretty obvious that I'm saying that there is evidence from the plaintiff's side to support that if the jury would so determine, that it was a genuine issue of material fact, and that's all.

MR. LEWIS: Understood. Okay. Thank you for that clarification, Your Honor.

Then secondly, also on the Court's order for motions to be discussed today was motion in limine No. 2.

It related to some --

THE COURT: I forgot all about that.

MR. LEWIS: -- financial information.

THE COURT: Yes.

MR. LEWIS: I didn't know --

THE COURT: I'm glad you brought that up. Yeah, I meant to take that up.

MR. LEWIS: Yeah, I wasn't sure. It really only requires brief discussion just on our side.

I think it's --

MR. CHILDERS: I don't think it would take long, Your Honor, if you want to hear it. In fact, I think it could be decided on the papers. But if they want to argue it, I'm happy to respond.

THE COURT: Well, briefly why don't you tell me what -- well, what evidence do you expect you would want to adduce that might fall within the motion?

MR. CHILDERS: The way I understand this, Your Honor, to be laid out, it would attempt to preclude plaintiffs from showing that there was any financial incentive for Boehringer to not include a therapeutic range or a cutoff value or information relating to blood plasma monitoring because that would create a competitive disadvantage, which I think you've seen in documents that we intend to show the jury.

We do think that that is proper evidence that goes to the motivation behind why this information was not put into the label, and it relates to competition, sales and money that would or would not be made by the company. So that would be I think appropriate for motive. It also goes to -- and intent.

It also goes to whether or not the jury would find that punitive damages may be appropriate. I think we have to be able to show the jury why it is a company may do these

things. And in this particular situation, we think the evidence shows that it was financially related. And then in that Your Honor has denied the summary judgment motion as it relates to punitive damages, obviously that type of evidence has to come before the jury if they do decide that punitives are appropriate.

THE COURT: There I would expect what you would offer testimony about the worth of the company.

MR. CHILDERS: In the punitive phase, Your Honor.

THE COURT: Yes.

MR. CHILDERS: What we have, though, in the initial phase of the trial is the company predicting --

THE COURT: Right.

MR. CHILDERS: -- we're going to make an X amount of money on this drug if it's not got monitoring, if it's the way we want it to be.

THE COURT: I don't recall that I addressed the bifurcation of punitives. Are you suggesting that that's what the Court ought to do?

I mean, that's typically what I do. And I'm only telling you that now because I haven't really thought about this other than just knowing of this motion and then forgetting that this was a motion we had.

Typically what I would say is that what you've described would be admissible evidence in your case in chief.

But once you get to the net worth, profitability and those factors in evidence about those matters, that that would be the subject of a bifurcated proceeding. And I would typically require first that the jury return a verdict and determine that you've proven the conduct that would merit consideration of punitive damages. And then if that's the case, we'd have hopefully what would be a relatively brief continuation of the proceedings while evidence of that came in, and then the jury would decide an amount.

MR. CHILDERS: That is certainly how I've seen it happen, and I think -- I don't know how you could do that and otherwise it not create a problem for all of us.

THE COURT: I agree.

So if it's limited the way we just described, does that alleviate the defendant's concern?

MR. LEWIS: It doesn't really, Your Honor.

THE COURT: Okay.

MR. LEWIS: And I think we'd like to have an opportunity to be heard on whether or not to bifurcate.

I'm not taking a position --

THE COURT: We will.

MR. LEWIS: Yeah, so I think we're not sure we'd want bifurcation --

THE COURT: Okay.

MR. LEWIS: -- with all due respect.

But that aside for a second, our main concern is that some of the financial matters are unfairly prejudicial, even if they're perhaps marginally relevant to some of the things that the plaintiffs want to use them for. And so what we're looking for is something consistent with what the court did in the Liu case, and we attached that order. Which is to say, look, don't get into financial matters in opening statements because the Court really can't control that at that point in time, and then give us a heads up on what particular things you want to get into, and we'll deal with those, you know, generally on a case-by-case basis.

For instance, there's a marketing video that they reference. I'd like the Court to have an opportunity to look at that and see -- you know, other courts have ruled and said that's not admissible.

So we just sort of don't want the cat out of the bag before we have a chance --

THE COURT: Okay. Well, I'll take a closer look at the motion and then may defer until we get back here for a pretrial at least as to some of the specifics.

MR. LEWIS: Fair enough. Thank you, Your Honor.

THE COURT: All right. Is there anything else that we need to take up on the record?

MR. CHILDERS: Nothing from the plaintiff, Your Honor.

MR. IMBROSCIO: Nothing, Your Honor.

THE COURT: If not, is anything changing about the settlement posture of the cases? I know this is only one of a handful or more.

How many cases do you folks have?

MR. MOSKOW: There are about 2,430 pending in Connecticut right now, Your Honor. There are approximately a dozen in St. Louis and approximately a hundred or so in California.

THE COURT: This can be off the record.

(Off the record.)

THE COURT: Thank you all for being here.

THE COURT SECURITY OFFICER: All rise. This honorable court is adjourned.

(Proceedings were concluded at 4:27 p.m.)

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CERTIFICATION:

I, Kathy L. Swinhart, CSR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on June 5, 2018.

June 21, 2018
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR